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UNIVERSITY OF ALBERTA

NURSES' PERCEPTIONS OF INFORMED CONSENT

BY

©

CHERYL A. KEE

A thesis submitted to the Faculty of Graduate Studies and Research in partial
fulfillment of the requirements for the degree of
Master in Nursing

FACULTY OF NURSING

Edmonton, Alberta
SPRING, 1994

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DEDICATION

To my husband Chris, and my daughters Erin and Allison, without whose support this endeavor would never have been accomplished.

ABSTRACT

Informed consent has been described as a process of shared decision-making between the physician and patient which involves mutual participation and a relationship of trust. Not all health care professionals understand or agree with the described responsibilities of physicians and nurses in the process of informed consent. As well, empirical nursing research on nurses' knowledge of and roles in informed consent is limited. A descriptive survey was conducted to identify nurses' knowledge of and practices in informed consent. Of the 225 nurses who responded from a stratified random sample of Alberta nurses, the majority indicated a general knowledge of the elements of informed consent. Inconsistencies were noted amongst nurses in the areas of witness to informed consent, disclosure of information for the purpose of informed consent, and responsibility for documentation of informed consent. Less than half of the nurses recognized the requirement of a witness was to only verify the patient's signature, while a number of respondents thought they should witness the physician-patient discussion. The majority of nurses agreed that information disclosure was the physician's responsibility; however, many nurses thought they could provide the patient with additional information if they perceived the patient was inadequately informed. Documentation of informed consent was recognized to only provide evidence of a discussion between the physician and patient. Many nurses agreed that documentation of informed consent was the physician's responsibility; however, a large number of nurses remained "unsure", or disagreed. Further education and research in the area of nursing and informed consent may be directed towards the role of witness to informed consent and documentation of informed consent. As well, research in the area of information disclosure may provide suggestions to improve information disclosure and enhance patient decision-making.

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CHAPTER ONE

Introduction

The fundamental element of informed consent was first described by Justice B. Cardozo in 1914 when he stated, "every human being of adult years and sound mind has a right to determine what shall be done with his own body" (Rosoff, 1981). Informed consent involves autonomous decision-making by patients based on the information they receive from the physician about their diagnosis, treatment, and care. Thus, informed consent is the disclosure of sufficient information by the physician about the nature of the illness, test, or procedure and includes the risks, consequences, alternative treatments, and the prognosis if the treatment is not undertaken. Informed consent can only be granted by a person who is legally and mentally competent and who, based on an understanding of the information disclosed, voluntarily agrees to the proposed treatment or procedure (Brown & Evans, 1989; Hogue, 1986; Rozovsky & Rovosky, 1990; Somerville, 1980).

A general definition of consent is "to give assent or approval" (Websters New Collegiate Dictionary, 1980). This description differs from the more current concept of a patient's "informed consent" which has evolved over the past number of years, mainly as result of court based decisions. Informed consent goes beyond agreement or acquiescence and may be described as a process or a "contract based on a special relationship of trust" (Rozovsky & Rozovsky, 1990, p.2) which involves shared decision-making by the physician and the patient (Carpenter & Langsner, 1975; Kyler-Hutchison, 1988; Nealon, Blumberg, & Brown, 1985; Taylor & Hobaugh, 1986) and is based on mutual participation (Carney, 1987). A specific legal definition of informed consent has not been developed because informed consent is not just to be obtained once thereby fulfilling legal obligations, but it is to be an ongoing requirement (Somerville, 1980). To specifically define such a concept may prematurely restrict the physician-patient relationship to that relationship which may be described in a definition of informed consent.

Informed consent has become a major part of patient care as a risk management tool for health care professionals and as a tool to facilitate patients' participation in their own health care. Most aspects of a patient's diagnosis, treatment, and care involve some kind of decision-making by them based on the information they receive from physicians. This is what forms the basis of informed consent.

Most of the medical, nursing, and medical-legal literature provides a description of the historical background of informed consent, the elements and criteria required for informed consent, the legal responsibilities of the physician, and the roles of nurses. The responsibility for informed consent rests with the physician (Rosoff, 1981; Rozovsky & Rozovsky, 1990; Storch, 1982) however, there appears to be some confusion about the roles of nurses. As well, not all health care professionals agree on what these roles encompass. Nurses have been described as patient advocates, responsible for assessing patients' comprehension of information, assessing their need for more information, clarifying the information that has already been given, reinforcing information, helping patients explore the meaning of that information related to their current situation, and supporting patients in their decisions once they are made (Bianco, 1991; Greenlaw, 1980; Storch, 1982).

In examining nurses' roles, a study by Carney (1987) revealed that physicians saw the nurse's role as one of education, while nurses saw their role primarily as one of patient advocate. Hypothetical vignettes have been used to identify nurses' roles described as a watchdog, an advocate, a resource person, a coordinator, and a facilitator (Davis, 1988). However, in this study, master's prepared nurses were used as a convenience sample and it is suggested that this group may be more knowledgeable about informed consent, and consequently sensitized to this topic. A need for information about nurses' perceptions of informed consent was also demonstrated by the findings of an informal survey of 149 physicians and 193 nurses, which was conducted by the Informed Consent Task Force at the University of Alberta Hospitals (1992). Staff frustration and confusion was evident in relation to medical and nursing roles in informed consent. Varied definitions and meanings of "obtaining consent" existed amongst medical and nursing staff and was restricted to giving information only, obtaining the signature only, or both giving information and obtaining the patient's written signature on the consent form. There did not appear to be a consensus among nurses for a description of a nursing role in informed consent.

In summary, empirical nursing research on nurses' knowledge, roles, and concerns about informed consent is limited. Despite an abundance of descriptive literature on the elements and criteria for informed consent, there is little research evidence to support the roles that have been described for nurses in informed consent. In practice settings, nurses are often in situations that require patients to give informed consent for medical treatment, medical or surgical procedures, and research or clinical trials involving drugs or procedures. In the current economic climate of decreasing health care budgets and rising health care costs, patients as consumers of health care, may have increased expectations of their health care providers. Nurses need to be aware of the legal foundations of informed consent in order to protect patients' right to know and their right to decide (Lynch, 1988).

Purpose of the Study

The purpose of this study was to (a) identify nurses' knowledge of the elements of informed consent, (b) determine the current practice of nurses in informed consent, (c) describe the frequency that nurses encounter informed consent in nursing practice, and

(d) determine the relationship of demographic and work related variables to the knowledge and practices of nurses in informed consent.

Significance of the Study

Determining nurses' knowledge of informed consent may assist in the development of specific content on informed consent for nursing education programs. The identification and clarification of nurses' roles in informed consent may be useful to assist other health care professionals understand nurses' perceptions of their role in informed consent and alleviate some of the confusion and frustration that may be experienced. The physician-patient-nurse relationship may be enhanced through a better understanding of nurses' knowledge and their practices in informed consent.

CHAPTER 2

Literature Review

The professional practices of medicine, nursing, and law have all had an affect on the development of informed consent. An historical overview highlights the key events that have resulted in the development of the "doctrine of informed consent". Case law that has played a pivotal role in defining and describing the elements of informed consent is described. The types of consent, the functions of informed consent, the elements of informed consent, physicians' and nurses' roles in informed consent will be presented.

Historical Background

"Informed consent" did not actually appear in modern medical literature until mid century, despite the references found that indicated patients were autonomous and self-determining as early as the beginning of the century. The basic principle of consent is found in the frequently cited statement by Justice Benjamin Cardozo in the case of Schloendorff v. Society of New York Hospital, 1914, when he stated that "every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages" (Buehler, 1990; Brown & Evans, 1989; Copeland, 1979; Cushing, 1991; Fiesta, 1988; Guido, 1988; Hogue, 1985; Kyler-Hutchison, 1988; Murphy, 1988; Rosoff, 1981; Sprung & Winick, 1989). Health care providers are thus obliged to honor the right of the person to make his or her own decision (Fabiszewski & Volosin, 1992).

Since that early time period, little else has been written with regards to patient consent to medical treatment until the late 1950's, early 1960's. According to Faden and Beauchamp (1986), in "A History and Theory of Informed Consent", only nine articles about consent in medicine were found in the published literature during that time. Nazi atrocities during World War II led to the development of the Nuremberg Code which was the first statement concerning the rights of persons involved in experimentation (Besch, 1979; Cassidy & Oddi, 1986; Chamorro & Applebaum, 1988; Davis & Aroskar, 1978; Davison & Davison, 1987; Douglas & Larson, 1986; Faden & Beauchamp, 1986; Garnham, 1975; Kravitz, 1985; Lynch, 1988; Perin, 1981; Silva, 1985; Van Lier & Roberts, 1986; Varricchio & Jassak, 1989; Watson, 1982). This Code resulted in physicians being responsible for obtaining informed consent from subjects prior to their inclusion in a study (Besch, 1979). As well, research should produce results "for the good of society, unprocurable by other methods of study" (Davis & Aroskar, 1978, p.69). Principle I of the Nuremberg Code further states that "voluntary consent means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision" (Douglas & Larson, 1986, p.43).

The principles of human experimentation first outlined in the Nuremberg Code were further developed in the Declaration of Helsinki which was adopted by the World Health Organization in 1964 (Davison & Davison, 1987; Kravitz, 1985; Watson, 1982). This code stated that research involving humans could not be conducted unless the importance of the research was in "proportion to the inherent risk to the subject" and that actions should be taken that would minimize the effect of the study on the person participating (Davis & Aroskar, 1978, p. 74).

The interest in informed consent appeared to arise from within the legal profession. Precedent setting cases in law alerted physicians both to informed consent "as a new legal development and to potential malpractice risk" (Faden & Beauchamp, 1986, p.88). The term "informed consent" was not actually "coined in case law" until 1957 and is thought to be a result of law, ethics, and medicine being affected by issues like those that occurred during the war and later in society (Faden & Beauchamp, 1986, p.87; Sprung & Winick, 1989). The Tuskagee syphilis study (1932 to 1974) involved adult Negro men with the disease syphilis. The disease was left untreated without their knowledge or consent in order to allow observation of the natural course of the disease. Another example of the need to protect patients from harm was demonstrated in the Jewish Chronic Disease Hospital where subjects were injected with live cancer cells. This was done in the guise of an immunity skin test and was for the purpose of observation of the body's reaction to this invasion but, it was done without the subjects' knowledge or consent. These types of situations prompted the government to take action against such unwarranted risks of physical harm to patients (Chamorro & Applebaum, 1988). The Patient's Bill of Rights (1973) was one such action which served to protect the interests of the patient (Cote, 1981; Faden & Beauchamp, 1986). In response to consumer demands for more accountability from health care providers, the Patient's Bill of Rights, which contains statements of what an individual can expect as a patient, was developed. The Patient's Bill of Rights also serves as a means of decreasing the incidence of malpractice claims that may arise from patient dissatisfaction with the hospital experience (Faden & Beauchamp, 1986). Some of the provisions include the right of the patient to current information regarding their diagnosis, treatment and prognosis, the right to information necessary to give consent, the right to refuse treatment, and the right to receive information about the hospital and its relationship with other health care facilities or institutions that may impact on their care (Faden & Beauchamp, 1986).

According to Katz (1986), physicians never had a duty to inform their patients based on the tradition of nondisclosure seen in the Hippocratic Oath.

Judges had no previous medical standards on which to base their legal decisions, therefore, their decisions created the precedents for the future of medical practice. The case of Salgo v. Leland Stanford, Jr. University Board of Trustees, 1957, was one such precedent setting case which found a physician negligent for not explaining the potential risks of a vascular procedure which resulted in the patient being paralyzed. This emphasized the patient's right to all the relevant information about a procedure (Besch, 1979; Guido, 1988; Plaut, 1989).

The purpose of "informed consent" is primarily to serve the interests of the patient and to "protect patients' right to thoroughgoing self-determination" (Davis, 1988; Davis & Underwood, 1989; Fry, 1989; Katz, 1986, p.94; Kyler-Hutchison, 1988). In the 1960 case of Natanson v. Kline, a physician had failed to warn the patient of the risks of radiation when she suffered burns as a result of excessive cobalt therapy (Banja & Wolf, 1986; Chamorro & Applebaum, 1988). The court established the physician's "obligation ... to disclose and explain to the patient in language as simple as necessary the nature of the ailment, the nature of the proposed treatment, the probability of success or of alternatives, and perhaps the risks of unfortunate results and unforeseen conditions within the body" (Katz, 1986, p.97). The court viewed this as a case of negligence where the physician failed to follow the standards of practice (Varricchio & Jassak, 1989).

Another well-known case is that of a 19 year old man who successfully sued a physician for negligence in failing to warn him of the one percent risk of paralysis following laminectomy surgery. After the man fell out of bed, he became paralyzed (a result of the complications) (Besch, 1979; Copeland, 1979; Creighton, 1986; Davis & Aroskar, 1978; Fiesta, 1988; Hogue, 1985). This landmark court case, Canterbury v. Spence, 1972, established a new standard of disclosure of information for physicians from the accepted "practitioner" standard to that of a "lay" or "reasonable man" standard (Hogue, 1985; Rosoff, 1981; Somerville, 1980; Trandel-Korenchuk & Trandel-Korenchuk, 1981). This new standard of information disclosure is patient-oriented, based on the need of the patient to receive enough information to make a decision to allow the proposed treatment (Schwabel, 1986; Trandel-Korenchuk & Trandel-Korenchuk, 1981). This disclosure includes whatever information patients in similar situations would consider "material" or important in making their decision (Copeland, 1979; Creighton, 1986; Hogue, 1985; Rosoff, 1981; Trandel-Korenchuk & Trandel-Korenchuk, 1981). "Any information that might cause a reasonable man to refuse treatment ...must be revealed to the patient" (Besch, 1979, p.33). It is felt that to respect the patient's right to self-determination there must be a standard set for physicians by the law (Katz, 1986; Schwabel, 1986).

Failure to obtain a patient's consent constitutes battery or negligence (Besch, 1979; Copeland, 1979; Rosoff, 1981). Battery is the intentional touching of a person without his or her consent and may include actions such as performing procedures or treatments beyond what was specified in the consent, providing treatment without consent, and consent that has been obtained through misrepresentation or fraud (Armstrong, 1988; Besch, 1979; Bianco, 1991; Chamorro & Applebaum, 1988; Cote, 1981; Finch, 1980; Hogue, 1985; Kutner, Ruark, & Raffin, 1991; Linden, 1982; Miller, 1981; Murphy, 1988; Pinfold, 1991; Sklar, 1980; Storch, 1982; Trandel-Korenchuk & Trandel-Korenchuk, 1981; Varricchio & Jassak, 1989). Most law suits related to lack of informed consent however, are based on negligence or the failure to inform the patient of a potential risk (Besch, 1979; Copeland, 1979; Guido, 1988; Hogue, 1985; Kutner et al., 1991; Linden, 1982; Murphy, 1986; Pinfold, 1991; Rothman & Rothman, 1977; Silva & Zeccolo, 1986; Storch, 1982; Trandel-Korenchuk & Trandel-Korenchuk, 1981; Varricchio & Jassak, 1989). In negligence, unlike battery, there must be an established link between the lack of information and the likelihood that the patient having known this information, would have refused to have the treatment or procedure (Armstrong, 1988).

The case of Cobbs v. Grant, 1972, required that the patient be given sufficient information about the treatment, risks, and alternatives to make an intelligent decision (Storch, 1982), and it described a differentiation between battery and negligence (Hogue, 1985). The patient in this case agreed to gastric ulcer surgery, which later resulted in complications that necessitated the removal of his spleen. Shortly thereafter, the patient was re-admitted several times with repeat gastric ulcers which were felt to be inherent risks of the previous surgery. A gastrectomy resulted which was complicated by post operative bleeding. All of these complications were felt to be inherent risks of each of the surgeries; however, they were not disclosed to the patient as possible risks (Besch, 1979; Copeland, 1979; Hogue, 1985). The physician has a duty to disclose the potential for death or serious harm, to explain in understandable terms any complications or problems of recuperation that may occur (Hogue, 1985). The underlying assumptions in Cobbs v. Grant are that patients generally are uninformed about medical science and therefore have less knowledge than physicians, that patients have the right to decide what treatments are undertaken, that consent to treatment must be informed to be effective, and lastly, that patients must depend on the physician for information. Therefore, it is the obligation of the physician to provide that information (Copeland, 1979; Ivey & Morris, 1993; Newhouse, 1993). "If a physician fails to advise a patient of a low-risk complication that could result from a procedure, and the complication subsequently develops, the trend is for the courts to hold the physician liable because of negligence" (Copeland, 1979, p.936).

Canadian courts have also set standards for physicians related to informed consent in the cases of Kelly v. Hazlett, 1976, Hopp v. Lepp, 1977, and Reibl v. Hughes, 1980. In Kelly v. Hazlett, the patient's consent was invalid because he did not understand the risks of the procedure and the physician was aware of this lack of understanding. The decision in this case was the basis of differentiation between battery and negligence, with negligence being a failure to inform the patient of risks that were not basic to the treatment, but collateral to it (Sklar, 1980).

In the case of Hopp v. Lepp, disclosure of information is not just related to the procedure and risks. The patient had a diagnosis of a slipped disc and had surgery; however, the patient did not recover as anticipated. Follow-up examinations indicated that the problem had not been relieved. Therefore, the patient was referred to another center where repeat surgery corrected the problem but, at the expense of nerve damage and disturbance of bowel and bladder function. The court findings indicated there was no difficulty with negligence on the part of the first surgeon in performing the procedure, nor in his failing to obtain an informed consent. The judge also thought that it was not necessary for the physician to disclose to the patient that this would be the first time he would perform this type of surgery alone (all other times occurring during orthopedic residency training). The difficulty in this case arose because the patient had asked the physician if the operation was serious and whether it should it be done in a larger city hospital. The original court decision was to dismiss the claim, but this was overturned in a Court of Appeal. It was thought that it was the physician's obligation to discuss the possible risks, the convenience and the expertise required in the surgery. The physician was found liable in battery (consent invalid because patient was not informed) and negligence (failure to meet the required standard of care in disclosure) (Sklar, 1980, p. 22).

Significant developments in Canadian law occurred with the case of Reibl v. Hughes, 1989, where decisions related to negligence and battery made in Kelly v. Hazlett were continued. The patient, Reibl, had a narrowing in the internal carotid artery which was discovered during investigations of headaches. This narrowing was felt to be unrelated to the cause of the headaches, however the recommendation was to correct this problem to reduce the chance of a stroke. Reibl underwent surgery and unfortunately suffered a major stroke leaving him paralyzed and unable to work. The risk of stroke associated with the surgery was 10 percent. However, Reibl alleged he had not been told of this risk and therefore the consent was not informed (Marshal & Nakatsu, 1991). The judge held that the degree of disclosure was negligent and that had the patient been informed of all the risks he may not have agreed to the surgery. The judge found that although consent had been obtained, it was not properly informed and therefore it was not valid (Sklar, 1980).

Several important areas were identified and the courts thought that the language describing negligence and battery was confusing and therefore should be "abandoned" (Linden, 1982, p.146). A result of this was to establish new standards for what would constitute negligence and battery. "If a physician fails to inform a patient of material risks associated with proposed treatment, this failure gives rise to a cause of action in negligence but does not vitiate the patient's consent so as to ground an action in battery" (Robertson, 1991, p. 424). The case of Reibl v. Hughes makes a distinction between battery and negligence, restricting battery to those cases where a treatment or surgery has been performed without consent or was performed beyond that which was consented (Robertson, 1991).

Standard of disclosure is another area of importance where the court ruled that "disclosure is to be measured by what a reasonable person in the patient's position would want to know, rather than by the traditional test of what a reasonable physician would decide to disclose" (Robertson, 1991, p. 425; Linden, 1982; Rozovsky & Rozovsky, 1990). This is an important point because the traditional assessment of negligence was based on what a reasonable practitioner would do or say in similar situations (Linden, 1982; Robertson, 1991). Henceforth, the courts now have a say in what will be appropriate information and patients will not be limited to what the physician chooses to disclose.

Lastly, the issue of causation was reviewed. The court decided that evidence of a link between the failure to disclose certain information and whether this information would have had an effect on the patient's decision to have the treatment or surgery, was required (Linden, 1982; Robertson, 1991). An "objective test of causation" must be used to decide if the patient would have consented to the procedure had he or she possessed all the information. It is this test that must be fulfilled before any compensation is awarded in cases of negligence in informed consent (Linden, 1982).

Informed consent has therefore, evolved to protect the patient's right to self-determination, and in doing so, the patient must have all the information that a reasonable person would need to know to be able to make an intelligent decision. History has shown us that medical practitioners have not always respected this right to choose; however, the law has now described standards that physicians must uphold in order to honor the patient's right to self-determination.

Types of Consent

Consent to treatment may be "expressed" explicitly through verbal or written consent or it may be implied. Expressed consent is when a person agrees to a specific procedure or treatment either verbally or by signing a piece of paper that describes the proposed treatment or procedure (Armstrong, 1988; Barkes, 1979; Bianco, 1991; Brown & Evans, 1989; Finch, 1980; Finch, 1983; Lewis & Warden, 1985; Linden, 1982; Miller, 1981; Miller, 1990; Newhouse, 1993; Sim, 1986; Thorpe, 1989). The written form of consent is more likely to be associated with those procedures that may be more painful, that are usually invasive, and that may carry more risk to the patient (Brown & Evans, 1989). Although verbal and written consent are considered to be equally valid, verbal consent is more difficult to prove in a court of law (Bianco, 1991; Cushing, 1984; Cushing, 1991; Flarey, 1992; Miller, 1981; Miller, 1990; RNABC News, 1987).

Implied consent is consent that is indicated by the behavior of the person (Armstrong, 1988; Barkes, 1979; Bianco, 1991; Brown & Evans, 1989; Miller, 1981; RNABC News; Sim, 1986; Thorpe, 1989). An example of implied consent is the patient who extends an arm for an intravenous insertion, the patient who accepts and takes the medication offered, and the patient who comes to the physician's office for a physical examination (Armstrong, 1988; Bianco, 1991; Brown & Evans, 1989). When there is doubt about consent that may be implied, it is recommended that consent be expressed either verbally or in written form (Brown & Evans, 1989).

Consent to treatment, whether implied or expressed, is usually obtained after the patient has received some sort of information or explanation and has been asked for their permission. The exceptions to this are those emergency situations when consent may be presumed and treatment is undertaken without the patient's expressed consent (Sim, 1986).

Purpose of Informed Consent

Informed consent functions to promote individual autonomy, protect patients, avoid fraud and duress, promote rational decisions, involve the public, and encourage self-scrutiny by medical professionals (Fry, 1989; Lewis & Warden, 1985; Makarushka & McDonald, 1979; Padberg, 1987). This means a physician cannot treat a patient until he has explained the facts of the treatment, the risks, and alternatives, including those of non treatment. The physician must receive permission voluntarily from a competent patient who understands the information (Copeland, 1979). The purpose here is to inform the patient, not just get a signature (Storch, 1982). A few authors have described informed consent as a "process of shared decision making between the patient and health professional that is based on mutual respect and participation" (Carney, 1987; Greenlaw, 1983; Kyler-Hutchison, 1988; Sprung & Winick, 1989; Taylor & Hobaugh, 1986). This process has been described as an educational process which involves open and honest communication between the patient and physician for the purpose of helping the patient to understand. This includes the disclosure of information, answering questions, and then signing the consent form (Cushing, 1991; Fiesta, 1991; Nealon, Blumberg, & Brown, 1985; Padberg, 1987). Carney (1987) believes that the informed consent process continues even beyond this exchange to include the "whole course of treatment" (p.253).

Some authors feel that a signed consent form protects the physician and the hospital against liability especially if the patient later claims that he or she did not agree to having a procedure or treatment, or that they were not told about specific complications (Besch, 1979; Makarushka & McDonald, 1979). For consent to be considered valid it must not have been obtained under fraudulent circumstances, under duress, or be obtained from someone who does not have the legal capacity to consent (Linden, 1982).

The basic assumption of informed consent is the belief that patients can secure more control over their body and life when they have the information on which to make their own decisions. Disclosure of relevant information provides patients with a sense of control (Miyaji, 1993).

Elements of Informed Consent

Throughout the literature, the elements of informed consent are listed individually or categorized into groups of elements or actions thought to be a part of informed consent. The elements described in most articles essentially all fall into the following categories which include a threshold element (competence or capacity), information elements (disclosure of information, understanding of information), and consent elements (voluntariness, authorization) (Beauchamp & Childress, 1989; Rozovsky & Rozovsky, 1987; Sprung & Winick, 1989).

Competence in Informed Consent

Competence can be defined as the "state of being competent" or "having sufficient ability" (Funk and Wagnalls Standard Desk Dictionary, 1976). It is described as a threshold element for informed consent which implies there are certain characteristics required for a person to be able to participate in the "process" of informed consent. Competence refers to the individual's ability to understand the information or explanation that has been given by the physician and it is related to the person's capacity to understand (Buehler, 1990; Beel-Bates, 1990; Brooke, 1988; Fiesta, 1991; Jakacki & Payson, 1985; Lynch, 1988; Sim, 1986). The capacity to consent must be present for informed consent to be considered valid, and it is related to age (over the age of majority) and mental competence (Hogue, 1985; Hogue 1986; Rozovsky & Rozovsky, 1987; Sklar, 1974). Most people are presumed to be competent unless they have formally been judged incompetent (Kutner, Ruar, & Raffin, 1991; Sprung & Winick, 1989).

The capacity or competence to consent is described as being able to "understand and weigh the risks against the benefits of the proposed conduct" (Brown & Evans, 1989; Cassidy & Oddi, 1986; Caplan, 1988). Persons who would be considered lacking the capacity to make rational decisions are those who are mentally impaired, minors (usually under 18 years of age), unconscious, incompetent, or otherwise unable, such as intoxicated persons (Brooke, 1988; Cassidy & Oddi, 1986; Guido, 1988; Mancini, 1979; Rozovsky & Rozovsky, 1990; Sklar, 1974; Youngner, 1986).

Factors that may affect competency include those physical elements of impaired vision, impaired hearing and mental changes especially those seen among the elderly population (Balkan, 1986; Bell, May, & Stewart, 1987; Buehler, 1990). Illiteracy and language is another factor, because if they cannot read or speak the language used in consent, then they are not capable of giving their consent (Balkan, 1986; Bell et al., 1987; Storch, 1982). Some authors think that a patient who has been premedicated for a test, procedure, or treatment should not considered competent (Murphy, 1986; Newhouse, 1993). However, competency does not remain stable in situations of pain, fatigue, and medication use. The level of competency may vary (Thorpe, 1989; Youngner, 1986) but despite these fluctuations, consents obtained while the person was lucid should be honored (Kutner, 1991). Because of the multidimensional factors that may affect the competence of the individual in their ability to consent, nurses and physicians need to make careful assessments of the person to ensure they are indeed competent to consent.

Nurses need to be aware of the competency issue mainly because they are often a witness to the patient signing the consent. According to Fromer (in Davis & Underwood, 1989), "the nurse is morally and professionally responsible to see that the client is competent to sign the form" (p.273). Nursing practice focuses on the competency of the individual to "take self-care action in regard to their respective health states" (Davis & Underwood, 1989, p.278).

There have been few empirical studies done in the area of competency. This may be related to the lack of a clear definition of competency as well as the fluctuating nature of competence, where a patient may be competent in one situation and not in another (Nusbaum & Chenitz, 1990).

Disclosure of Information in Informed Consent

Some authors describe a legal standard for disclosure of information where there is a set "minimum level of expected behavior" and an ethical standard of information where disclosure would "aim for the ideal" and would usually require greater information than the legal minimum. It would be expected that these information demands would not necessarily be in conflict; however, the ethical standard would involve more information (Cassidy & Oddi, 1986; Fowler, 1987, p.415).

Any information that is given to patients should include all the information that may be relevant to the procedure, especially if it might be of the nature that a "reasonable man" might refuse the treatment (Allen, 1990; Besch, 1979; Bianco, 1991; Brown & Evans, 1989; Hogue, 1985; Hogue, 1986; Kyler-Hutchison, 1988; Linden, 1982; Mariner & McArdle, 1985; Meade & Howser, 1992; Miller, 1990; Murphy, 1986; Newhouse, 1993; Rothman & Rothman, 1985; Sim, 1986; Sprung & Winick, 1989; Trandel-Korenchuk & Trandel-Korenchuk, 1981). The information provided must be usable in making a decision. The nature of the disclosed information is such that it should include information about the diagnosis, a description of the proposed treatment, the rationale for the treatment, the reasonable alternative forms of treatment, a description of potential risks, an explanation of the benefits, the probability of the treatment's success and the prognosis if proposed treatment is not followed (Banja & Wolf, 1986; Besch, 1979; Brent, 1990; Brown & Evans, 1989; Cassidy & Oddi, 1986; Copeland, 1979; Cushing, 1984; Cushing, 1991; Davison & Davison, 1987; Fabiszewski & Volosin, 1992; Farkas, 1992; Fiesta, 1991; Flarey, 1992; Fry, 1989; Greenlaw, 1980; Greenlaw, 1983; Holder & Lewis, 1981; Jakacki & Payson, 1985; Kyler-Hutchison, 1988; Lewis & Warden, 1985; Linden, 1982; Lynch, 1988; Mariner & McArdle, 1985; Miller, 1981; Moskowitz & Moskowitz, 1986; Murphy, 1986: Newhouse, 1993; Perin, 1981; Peterson, 1987; Plaut, 1989; Rabinow, 1983; Raudonis & Kirschling, 1992; Rothman & Rothman, 1977; Rovosky & Rozovsky, 1987; Schwabel, 1986; Silva & Zeccolo, 1986). Other elements of informed consent include allowing the patient time for questions and the opportunity to refuse or withdraw at any time (Besch, 1979; Newhouse, 1993; Peterson, 1987; Rozovsky & Rozovsky, 1990; Sklar, 1974; Sklar, 1980).

The disclosure of information does not intend the physician to explain every single detail of the procedure and all the things that could go wrong. Physicians do not wish to unduly upset or frighten patients with unnecessary information (Fowler, 1986; Linden, 1982; Roling, Pressgrove, Keeffe, & Raffin, 1977; Sklar, 1980). The explanation would probably not include the "ordinary risks" of surgery such as bleeding, scarring, or pain unless the procedure is experimental or being done for cosmetic purposes where a greater degree of disclosure is required. The "frequency of the risk becomes much less material when the operation is unnecessary for (the patient's) medical welfare" (Linden, 1982, p.147; Roling et al., 1977; Sprung & Winick, 1989) or when a procedure is complicated. In this case then, the physician has a duty to disclose the potential for death or serious harm (Copeland, 1979).

In one of the earliest studies of informed consent, Alfidi (1971) looked at the impact of information about coronary angiography on patients' agreement or refusal to have the procedure. Two information forms about coronary angiography were given to the patients prior to their test, with a questionnaire included to ascertain their reactions to the information. Only two percent of the subjects refused to proceed with the angiogram based on the information they had received, and their replies led Alfidi to conclude that "the majority of patients not only have a right to know but want to know what possible complications may be expected from any given procedure" (Alfidi, 1971, p. 1329). Other findings indicated that straight forward explanations about complications resulted in few patients refusing the procedure. They did suggest that the information would probably be better provided more in advance of the procedure (Alfidi, 1971).

Another more recent study, also involving cardiac catheterization (1981), looked at the effects of informed consent and educational sessions on patient knowledge, anxiety, and subjective responses to the test (Freeman, Pichard, & Smith, 1981). The authors identified areas of concern for patients undergoing cardiac catheterization which included the duration of procedure, limitation of their activities, and the number of procedures. The findings indicated that less abstract information sessions were more effective for those patients without college education and that many patients did not understand the meaning of "heart attack" and some other related terms, indicating that more education in this area may be required (Freeman et al., 1981).

The basis for many decisions regarding informed consent rests with "material risk" which is "one which a physician knows or ought to know would be significant to a reasonable person in the patient's position in deciding whether or not to submit to a particular medical treatment or procedure" (Brown & Evans, 1989; Copeland, 1979, p. 942; Creighton, 1986; Fowler, 1986; Mariner & McArdle, 1985; Murphy, 1986). Material risks are based on whether or not the reasonable patient accepts the risks and then chooses to undergo or refuse the treatment. If a patient asks questions about a procedure, or the recovery from a procedure, the physician is obligated to respond to these questions and fully inform that patient (Linden, 1982).

Meisel and Roth (1981) cite a study by Faden and Beauchamp which looked at whether or not information disclosed may have a "harmful" effect on patients and they discovered no negative consequences appeared related to information disclosure. Reactions to full disclosure of information to endoscopy indicated that only about one third of the patients thought this increased their apprehension, even though they all agreed to the procedure (Roling et al., 1977). A review of patients' attitudes about risks of contrast-enhanced computerized tomography and intravenous urography indicated that only 23% of the subjects were more anxious with information about risks and only 10% preferred not to have this information (Spring, Winfield, Friedland, Shuman, & Preger, 1988). Other investigators reported that certainly some patients suffer anxiety and apprehensiveness with disclosure; however, patients who were better informed were usually less anxious (Meisel & Roth, 1981). In contrast however, one study reviewed attitudes toward having a cerebral angiogram and the author found that 50% of the subjects would have withheld their consent because of knowledge of the complications (Rosenberg, 1973). The difficulty in this study was the use of subjects who were not actually going to have the procedure but who were asked to respond as if they were, and it might be suggested that their responses would be different had there been a medically demonstrated need and if their physician had recommended the procedure. In their review of several empirical studies on informed consent, Meisel and Roth (1981) determined there was no real conclusive evidence about the feasibility of informed consent because of the methods and conceptual difficulties within the studies.

The exceptions to disclosure of information for the purpose of informed consent are those situations requiring emergency care, or when the patient requests not to receive the information (waives the right to information), or when the disclosure would so upset the patient that it would interfere with their ability to make an intelligent decision (Applebaum, Lidz & Meisel, 1987; Beauchamp & Childress, 1986; Copeland, 1979; Guido, 1988; Miller, 1990; Plaut, 1989; Rosoff, 1981). Another aspect of disclosure of information is the manner in which the information is shared. The information must be delivered in a way that the patient can understand the information (Cassidy & Oddi, 1986).

Consequently, the disclosure of information requires physicians to explain all the necessary information that a reasonable person would need to know related to the procedure and the material risks, in terms that patients can easily understand. Research in the area of information disclosure revealed that the majority of patients usually want to know the complications that may be related to a procedure. Despite the small number of patients who report being more anxious after receiving the information, most of them consent to the proposed treatment or procedure and are more informed about what is involved.

Comprehension of Information in Informed Consent

In claiming that informed consent is ineffective, some critics suggest that patients do not understand the information they are given, nor do they use it for the purpose of making the decision (Applebaum, Lidz, Meisel, 1987). Sometimes patients rely on the physician's decision to do the "best thing" and in doing so, they relinquish their right to consent to the physician (Applebaum, Lidz, Meisel, 1987). However, for the purpose of informed consent, information disclosure itself is not enough. There must be understanding of that information. Studies using recall of information are used to support the position that understanding of medical information is not achieved by patients (Applebaum, Lidz, Meisel, 1987). This appeared to be an issue as early as 1969 when Epstein and Lasagna studied ways of communicating information to volunteers who were to decide if a study drug was safe for them to use. They found that "comprehension and consent to volunteer were inversely related to the length of form" with the subjects who read the shorter version being able to recall more of the important facts (Epstein & Lasagna, 1969, p. 684). Their data indicated that to aid comprehension and more intelligent decision-making, information should be brief and to the point. Patient understanding has been associated with the amount of information presented, with the more detailed and lengthy explanations leading to less comprehension and in some cases producing unwanted anxiety (Besch, 1979; Cassidy & Oddi, 1986).

Recall of information for the purpose of measuring patients' comprehension is not necessarily a true indication that the patient did or did not understand the information at the time they made their decision (Applebaum, Lidz, & Meisel, 1987; Arbeiter, 1988; Cassidy & Oddi, 1986). It is also possible to recall the facts without having an understanding of the implications of having the test, treatment or procedure. Leeb, Bowers, and Lynch (1976) conducted a study to assess patients' recall of information and the findings indicated that overall recall one week later was poor, despite claims that they understood the information at the time. Similarly, another study demonstrated that patients failed to recall potentially lethal complications and the authors concluded that patients do not adequately comprehend information (Cassileth, Zupkis, Sutton-Smith, & March, 1980). In another study, Robinson and Merav (1976) found that patients had poor recall of information four to six months after surgery; however, this could be attributed to forgetfulness, especially at these lengths of time after the procedure. These results provide evidence that recall may be a poor endpoint in measuring understanding at the actual time of consent.

Silva (1985) assessed spouses' comprehension of information related to their husband's or wife's surgery, with the assumption that comprehension could be indicated by the scores on a recall test. Adequate comprehension of information was indeed demonstrated; however, factors that presented a limitation of this study, were the small non probability sample and the use of a new assessment instrument.

Comprehension of information may also be enhanced in patients with higher education levels (Cassidy & Oddi, 1986). An interesting finding in one study was a positive relationship between higher levels of education and a better retention of information, and the observation that patients who considered themselves to be "nervous" remembered information better than those who were "calm" (Leeb et al., 1976).

Mariner and McArdle (1985) looked at ways to assess comprehension for consent by using readability tools as a measure of comprehension. Assessment of the subjects' understanding of information was undertaken using a vaccination information sheet upon which they were asked to indicate their consent by signing the form. The authors discovered that the use of readability tools as a measure of comprehension was "insufficient and even inappropriate" (Mariner & McArdle, 1985, p. 71) generally restricted to assessing the reading difficulty of the document. They identified the major limitation of these tools as the inability to effectively assess comprehension. The authors suggest that a document with a good visual format, that is legible, and well laid out may assist in comprehension. In a review of readability estimates of consent to a clinical trial in cancer, Meade and Howser (1992) found that the mean consent form reading level was grade 14.3, or a professional reading level. This suggests that there needs to be some improvement in the reading ease of consent documents.

Nurses and physicians need to be aware of those factors which may enhance or inhibit the understanding of information. Information perceived as too threatening, too complex, insufficient or unclear, may inhibit comprehension (Cassidy & Oddi, 1986; Kyler-Hutchison, 1988). Sufficient information, clearly presented in understandable language, and allowing for time to make a decision, appear to be factors that may enhance comprehension. Sorrell (1991) summarizes a few of the studies on comprehension and described factors that may inhibit comprehension of information. These factors are the complexity of the information, the amount of the information (too much or too little), whether the information is perceived as threatening, and if it is presented by the physician alone. Poor comprehension is associated with subjects who are not motivated to receive information for consent and with those subjects who have lower vocabulary and education levels (Sorrell, 1991). Some suggestions for improving the lack of comprehension in informed consent include the consideration of the length of the consent form, the time that may be required to consider the information, the timing of the information prior to the procedure (Meisel & Roth, 1981), and inadequate or inconsistent disclosure of information (Cassileth et al., 1980). A direct and brief presentation of information, usually by a health professional, obtaining immediate recall of the information, and allowing the subject to keep the written information are suggestions to promote comprehension of information (Sorrell, 1991).

Voluntariness in Informed Consent

A fundamental principal of informed consent relates to the voluntary participation of the person (Kravitz, 1985). Voluntariness, or the ability to exercise one's will (Kjervik & Grove, 1988), is valid in consent only if it is freely and voluntarily given (Applebaum, Lidz, & Meisel, 1987; Armstrong, 1988; Besch, 1979; Beuhler, 1990; Brooke, 1988;

Cassidy & Oddi, 1986; Douglas & Larson, 1986; Fry, 1989; Youngner, 1986). To be voluntary, there must be no influence from external sources and it should be "free from coercion, unfair persuasions, and inducements" (Besch, 1979, p.33; Brooke, 1988; Fry, 1989; Hogue, 1985; Hogue, 1986; Kyler-Hutchison, 1988; Plaut, 1989; Rozovsky & Rozovsky, 1990; Silva & Zeccolo, 1986; Sim, 1986; Sklar, 1974; Sprung & Winick, 1989; Trandel-Korenchuk & Trandel-Korenchuk, 1981; Youngner, 1986). Influences on the voluntary nature of informed consent may come from many sources and these are primarily coercion, manipulation, and persuasion (Beauchamp & Childress, 1989). The forms of influence can be described as being on a continuum with coercion at one end, and persuasion, a weaker form of influence, at the other end. Coercion has been defined as "when one person intentionally uses a credible and severe threat of harm or force to control another" (Beauchamp & Childress, 1989, p.107). Persuasion, on the other hand, convinces someone to believe in something based on the reasons that are given by another person. Manipulation however, is that influence which is really not coercive or persuasive but is getting people to do what you want; for example, by managing information through lying or withholding facts (Beauchamp & Childress, 1989).

In very few studies was voluntariness examined; however, those that did, indicated that other influences; such as family or economics, can affect the voluntary ability of the subject. Kidney donors appeared to be influenced by their family system and mothers of children who required hospitalization, felt they had "no choice" (Meisel & Roth, 1981).

Physical and emotional stress may render patients unable to listen to information, to ask questions, or to understand information in order to make a decision (Carpenter & Langsner, 1975; Farkas, 1992;). Illness and pain may not be seen as any stronger an influence than any other life factors which may influence a patient's decision-making, such as family influences, parenthood, financial difficulties, overextended business, or professional schedules (Fowler, 1987). The physician may also be seen as a coercive influence simply because of his or her authoritarian role (Besch, 1979; Carpenter & Langsner, 1975; Fowler, 1987).

A study cited in Besch (1979) was conducted to assess reasons for consent among women who agreed to having an experimental drug for inducing labor. The findings indicated that forty percent of the subjects did not realize they were in a study and forty-one percent had no idea of the risks involved . "Patients tended to trust their physician's recommendations completely" and many subjects did not realize they were the ones required to make a decision (Besch, 1987, p.34). It was thought that patients who did not ask questions about the study did so because they thought their physician might view this as mistrust and they would lose their physician's support (Besch, 1979).

Internal factors which may interfere or hinder an informed consent are those of habit, impulse, and compulsion. Impulse choices may frequently be made by those choosing weight loss or stop smoking programs and habits, such as drug use, may outweigh intelligent decision-making. Altered mental states related to psychiatric disorders, drugs, electrolyte imbalances, and hypoxia may result in the patient being unable to participate in decision-making.

Voluntariness is difficult to study empirically because of the complex nature of the concept and the difficulty in methods of measurement to assess the presence or absence (Meisel & Roth, 1981; Nusbaum & Chenitz, 1990). The patient's right to decide may be impaired by those external and internal factors discussed and physicians and nurses must be cognizant of these influences on the voluntariness and the informedness of the patient from whom he or she wishes to obtain an informed consent.

Physicians' Responsibilities in Informed Consent

The words role and responsibilities are often used interchangeably. For the purpose of differentiation, a "role" is that function or action of the physician or nurse to care for the patient; and a "responsibility" is the state of being accountable or answerable legally for the discharge of a duty (Funk & Wagnalls Standard Desk Dictionary, 1977). Obtaining consent refers to the "exchange of information that takes place in the consent process between caregiver and patient" (Rozovsky & Rozovsky, 1990, p. 15).

The responsibility for obtaining informed consent lies with the physician (Allen, 1990; Arbeiter, 1988; Armstrong, 1988; Banja & Wolf, 1987; Bianco, 1991; Brooke, 1988; Carney, 1987; Curtin, 1982; Cushing, 1984; Douglas & Larson, 1986; Fabiszewski & Volosin, 1992; Greenlaw, 1980; Hershey, 1965; Mancini, 1979; Miller,1981; Miller, 1990; Murphy, 1986; Regan, 1980; Rothman & Rothman, 1977; Schrader, 1973; Varricchio & Jassak, 1989; Weikel, 1987; Whalen, 1984) and "cannot be delegated to the nurse" (Allen, 1990, p.425; Bujorian, 1988; Creighton, 1986). Some authors specify it is the responsibility of the physician who will be performing the treatment or procedure to ensure that disclosure of information is carried out (Brown & Evans, 1989; Hudson, 1991; Greenlaw, 1983; Murphy, May 1988; Newhouse, 1993; Silva & Zeccolo, 1986; Taylor & Hobaugh, 1986). In a study by Carney (1987), five physicians and sixteen nurses were interviewed about their roles in informed consent for bone marrow transplantation. The findings indicated that the principal roles for the physician in informed consent included information giving, validation of patient understanding, and team leading, in that order. The physician's responsibilities included informing patients, obtaining patient consent, and maintaining objectivity in the process of obtaining informed consent (Carney, 1987). It appeared that physicians viewed informed consent as a process that included active patient participation, and they also agreed this participation was the patient's responsibility (Carney, 1987).

Some authors state the authority to obtain informed consent may be delegated from the primary physician to another physician, but the responsibility of obtaining the informed consent remains with the primary physician (Bianco, 1991; Brown & Evans, 1989; Holder

& Lewis, 1981; Miller, 1990; Murphy, 1986). However, when the physician delegates the responsibility for informed consent they are relying on another physician's judgment and they may not know how well this physician will present or explain the information (Hudson, 1991). One author states that the responsibility of the physician "cannot be delegated" (Regan, 1980, p.77).

Physicians often overestimate the amount of involvement in decision-making their patients desire and underestimate the desire for information (Brody, 1989). Consent should be individualized to suit the needs of each patient and should be viewed as a "process of giving and receiving information, not as a physician's protection against possible lawsuit" (Besch, 1979, p.35).

Few researchers have examined the physician's responsibility in informed consent; however, of those that did, the described responsibilities appeared to be informing the patient, validating the patient's understanding, and obtaining the patient's informed consent (Carney, 1987). However, the sole responsibility for informed consent is the physician's.

Nurses' Responsibilities in Informed Consent

The nurse's role may complement the role of the physician, working cooperatively towards ensuring the patient is informed (Schrader, 1973). However, nurses should be cautioned against providing patients with information regarding a test, procedure, or treatment because if they do, they will be undertaking the duties of another professional, mainly the physician's. Nurses who do take on this responsibility will be held to the standard of disclosure of the physician and therefore, should be discouraged from this activity (Murphy, May 1988). Others hold the position that "clarifying and reinforcing the medical information is well within the nurse's domain" (Bujorian, 1988, p.782; Carney, 1987; Cote, 1981; Fabiszewski & Volosin, 1992; Greenlaw, 1980; Lynch, 1988; Varricchio & Jassak, 1989; Weikel, 1987).

Nurses are thereby able to answer questions about a test, procedure, or treatment as long as it does not go beyond the explanation given by the physician (Creighton, 1986; Fabiszewski & Volosin, 1992; Greenlaw, 1980; Hershey, 1965). In Tuma v. Board of Nursing, a nurse gave a cancer patient information about alternative treatments, going beyond what the physician had disclosed which created a conflict with the physician. This resulted in the suspension of her nursing license (Creighton, 1986; Kravitz, 1985; Weikel, 1987). Chamorro and Applebaum (1988) conducted a study that looked at nursing disclosure of information and found that nurses do play a significant part in providing information to patients through "incidental disclosure", however there was no explicitly defined role. The patients in this study did not identify the information they received from the nurses as having an effect on the informed consent process. Nurses were noted to provide patient education with a focus on the procedure and its related discomforts without specifically addressing issues of risk, benefit, and alternative therapy (Chamorro & Applebaum, 1988).

It is important for nurses to be able to assess patients' understanding and be able to evaluate patients' retention and comprehension. This may assist in identification of those areas that could use reinforcement (Brent, 1988; Bujorian, 1988; Chamorro & Applebaum, 1988; Greenlaw, 1980). Nurses can minimize the factors that may interfere with understanding through the use of educational aids to present information in a manner more easily understood, the use of translators if a language barrier exists, and ensuring the patient is comfortable and as free from pain or anxiety as possible (Taylor & Hobaugh, 1986). If it becomes apparent that a patient does not understand the information, then the nurse should convey this information to the physician so that he or she can intervene as required (Miller, 1990; Murphy, May 1988; Schrader, 1973; Sklar, 1974).

Nurses must provide patients information related to nursing procedures and nursing care (Greenlaw, 1980; Lynch, 1988; Weikel, 1987; Taylor & Hobaugh, 1986).

A survey of critical care nurses' opinions on informed consent related to the insertion and maintenance of a pulmonary artery catheter revealed that nurses were more concerned with patients receiving information on the discomfort associated with the procedure, rather than risks or benefits of the procedure. The author felt that a legitimate role for nurses in informed consent would be to explain those procedures for which nurses have primary responsibility (Whalen, 1984).

Nurses are also said to be in a position to protect the patient's right to an informed consent (Banja & Wolf, 1987; Greenlaw, 1980). Their frequent contact with the patient and knowledge of the patient's situation may provide them a position from which to determine if the physician has completed his responsibilities in obtaining a voluntary informed consent and to institute corrective measures if needed (Banja & Wolf, 1987; Chamorro & Applebaum, 1988; Copeland, 1979; Hershey, 1965; Sklar 1974; Storch, 1982; Taylor & Hobaugh, 1986).

Nurses can assist patients and their families in exploring their feelings about their situation and in doing so, they may be able to assist patients in their decision. Nurses can support patients in their right to make this decision (Brooke, 1988; Bujorian, 1988; Carpenter & Langsner, 1975; Douglas & Larson, 1986; Trandel-Korenchuk & Trandel-Korenchuk, 1981). Nurses can remind patients that the responsibility for the consent decision is theirs to make (Carpenter & Langsner, 1975) and that they have the right to receive information necessary to make that decision (Greenlaw, 1980).

The role of patient or client advocate bears many descriptions. Some of the associated responsibilities have been identified to include notifying the physician if the patient does not appear to understand the information (Cote, 1981; Schrader, 1973; Storch, 1982), and protecting the patient's right to give an informed consent (Brooke, 1988; RNABC News, 1987; Wells, 1986; Silva & Zeccolo, 1986). Activities of a "client advocate" might also include "helping the client to be clear about desires, to make decisions based on individual values and goals, and to communicate these values, goals, and decisions to the entire healthcare/research team" (Lynch, 1988, p. 26). Support for the client's decision involves ensuring that they have sufficient information and that they have time to ask questions and receive answers (Lynch, 1988).

In a study by Barkes (1979), ten oncology nurses completed a questionnaire identifying their perceptions of and their experiences with informed consent. The findings indicated that most nurses agreed their primary role was that of "patient advocate" to support the patient in his/her decision, to witness signing the consent, and to interpret for the patient if there was a misunderstanding of the information. Nurses felt if they were dissatisfied with the patient's degree of comprehension, further explanation should be given by the physician. The nurses appeared to be more comfortable if the patients were informed rather than if they desired to remain uninformed (Barkes, 1979). Considering the small sample size and the year in which it was conducted, some of the findings may not be as relevant to nursing practice today.

Carney (1987) interviewed sixteen nurses and five physicians in regards to their roles and responsibilities in informed consent related to bone marrow transplant. The findings indicated that nurses' roles included patient advocate, patient educator, and patient supporter. Physicians saw nurses primarily as patient educators while the nurses perceived themselves primarily as patient advocates. They described responsibilities of a patient advocate that included clarifying and expanding the information that had been presented by the physician. Nurses appeared to be more concerned about side effects and complications of the treatment, and saw patients more as a passive receiver of information, not as an active participant (Carney, 1987). This study illustrates a few of the described roles and responsibilities of nurses in informed consent providing some empirical evidence for nursing actions in informed consent.

Some authors have described a responsibility for nurses that includes the clerical duties of ensuring the consent form has been signed and the form properly completed (Balkan, 1986; Copeland, 1979; Creighton, 1986; Miller, 1981; Miller, 1990; Newhouse, 1993; Regan, 1980; Rozovsky & Rozovsky, 1987; Rothman & Rothman, 1977; Sklar, 1974).

In a study by Lidz (in Cushing, 1984), the nursing responsibilities in informed consent identified were teaching, counseling, and clarifying. The nurses identified disclosure as the physicians responsibility and stated that nurses should not be designated to provide medical information for the purpose of consent. Another study using hypothetical vignettes resulted in a description of nursing roles, which comprise a watchdog, an advocate, a resource person, a coordinator, and a facilitator (Davis, 1988). The role of "watchdog" involved monitoring consent situations, usually by being present during the discussion and ensuring adequate consent was obtained. As an "advocate", nurses mediated on behalf of the patient, bringing new information to physicians and supporting the decisions made by patients. Nurses, as "resource persons", clarified the features of consent, and collected and reported information about alternatives available. As the "coordinator", nurses integrated treatment and the care of patients while exploring the implications and effects of this on patients and their family. Lastly, as a "facilitator", nurses clarified and validated the views of the people involved in informed consent, including arranging meetings to discuss situations of consent (Davis, 1988). Twenty-eight Master's prepared nurses were subjects of this study and it is suggested that this group may be more knowledgeable about informed consent, and consequently sensitized to this topic.

Taylor and Hobaugh (1986) succinctly state that the nurse's role in "fostering informed consent includes respecting well-being and self-determination, promoting adequate disclosure, assessing comprehension and competence, and facilitating voluntary choice" (p.99).

Witness to Informed Consent

Witness to informed consent is frequently referred to in the literature with many different opinions. A few authors simply state that witness of informed consent is part of the nurse's responsibility (Balkan, 1986; Fabiszewski & Volosin, 1992; Lynch, 1988; Miller, 1981; Northrop, 1986). The traditional approach to the responsibility of witness to consent has simply been to verify the patient's signature, but not to verify that the patient made an informed decision (Armstrong, 1988; Brooke, 1988; Brown & Evans, 1989; Chamorro & Applebaum, 1988; Creighton, 1986; Cushing, 1984; Greenlaw, 1983; Murphy, May 1988; RNABC News, 1987; Varricchio & Jassak, 1989; Weikel, 1987), or verifying the degree of disclosure (Varricchio & Jassak, 1989). In this situation, it may be documented that it is "witness as to signature only" (RNABC News, 1987, p. 21). A nurse-lawyer states that "witnesses merely attest to the competency of the patient signing the form and to the genuineness of the signature" (Guido, 1988, p. 79), implying that nurses still do not verify the decision, but can state the patient was competent at the time consent was given (Holder & Lewis, 1981).

Some nurses think that in witnessing the consent it somehow makes them liable for the consent being sufficiently informed (Bianco, 1991) Also, some authors state that nurses can witness the patient's signature as a legal duty, and an ethical duty may be to ask the patient if he or she has discussed the procedure with the physician and if so, did they understand the information (Calfee, Cauffman, & Taylor, 1991; Chamorro & Applebaum, 1988; Murphy, May 1988; Newhouse, 1993; RNABC News, 1987; Rothman & Rothman, 1977; Taylor & Hobaugh, 1986). If it appears that the patient did not understand the information, the nurse's responsibility is not to provide missing information, but to notify the physician and ask him or her to speak with the patient again (Brown & Evans, 1989;

Calfee et al., 1991; Carico & Harrison, 1990; Carpenter & Langsner, 1975; Hershey, 1962; Holder & Lewis, 1981; Greenlaw, 1983; Murphy, May 1988; RNABC News, 1987; Rozovsky & Rozovsky, 1987).

This position is also supported by nursing responsibilities in informed consent that were discussed in a survey by Arbeiter (1988). Some of the findings indicated that nurses view witnessing a consent as authenticating a patient's signature but not the degree of comprehension. However, many nurses thought that it is "morally and ethically wrong" to participate in uninformed consent (Arbeiter, 1988, p.54), and they refused to witness the consent if they thought the patient did not understand the information. The nursing role is one of an "intermediary", whether it is to contact the physician or to advise the patient to follow-up with the physician. If the patient appeared not to understand the information, the nurse would suggest to the patient to get more information from the physician and this was thought to "discharge an ethical duty" (Arbeiter, 1988, p. 54). A nurse who provides information to a patient is placing him or herself at risk for liability especially if the information provided was inaccurate, and he or she may be also be accused of interfering in the physician-patient relationship (Arbeiter, 1988).

Fiesta (1991) describes witness as "the observer who sees the physician obtain the patient's signature" because the physician cannot be his or her own witness (p.17). The nurse who obtains the patient's signature is not a witness, but is the person who is actually obtaining the signature (Fiesta, 1991). This opinion reflects those authors who perceive physicians as having a conflict of interest if they act as a witness to consent (Fiesta, 1991; Murphy, June 1988). To further confuse the issue of witness to consent, some institutions do not allow nurses to act as witness to informed consent in case inadequate information has been provided or there are difficulties in obtaining patient's signatures that would shift the responsibility of informed consent to the hospital, as the nurse's employer (Miller, 1990; Rozovsky & Rozovsky, 1987). There is no legal requirement for a witness, however, it is a good risk management tool and using a patient's family member as a witness would "be ideal" because it would be difficult to prove that informed consent had not been obtained (Fiesta, 1991, p. 18).

Consequently, the responsibility of witness to informed consent may or may not rest with physicians, nurses, family members, or the role of witness may not truly be necessary. The evidence as seen in the literature certainly does not indicate a consensus of opinions in this area.

Documentation of Informed Consent

According to Curtin (1982), the "legal doctrine of informed consent arose to protect patients, the consent form arose to protect providers" (p.7). A consent form is a tool to simplify the procedure of informed consent because it was thought that without a consistent format for physicians to follow, necessary information might be omitted; although this creates additional work for nurses searching the chart to see if consent has indeed been obtained (Fiesta, 1991; Hudson, 1991). A review of Quality Improvement data for the Division of Cardiology at the University of Alberta Hospitals was conducted for a nine month period. One of the main areas identified for improvement was documentation and the largest proportion (34%) of that documentation was related to the documentation of informed consent (Tsang, 1993).

Written consent is evidence of consent and it can be "undermined with evidence of fraud, duress, lack of capacity, and other similar circumstances" (Linden, 1982, p.58; Greenlaw, 1983). It is nothing more than evidence that a conversation took place between the named physician and patient, on a particular day, at a particular time. It is not a substitute for the consent process, nor does it obligate the patient to carry out with the proposed treatment or procedure (Brown & Evans, 1989; Cote, 1981; Cushing, 1991; Hogue, 1985; Hogue, 1986; Holder & Lewis, 1981; Miller, 1990; Moskowitz &

Moskowitz, 1986; Rozovsky & Rozovsky, 1990; Sklar, 1974). It is more often viewed as a formality required by the institution (Cushing, 1984).

One suggestion for documentation of informed consent included the practice of having nurses present during the physician-patient discussion so they may attest to what was said; but, it is thought that the burden for documentation of this discussion does not rest with nurses (Cushing, 1984). Another suggestion is to have the physician obtaining the consent to chart the consent in the progress notes which may also improve the credibility of the consent (Rozovsky & Rozovsky, 1990).

In a study cited in Chamorro and Applebaum (1988), it was found that consent forms are too complex and phrased in such medical jargon that patients are prevented from being able to provide an intelligent informed consent. Curtin (1982), suggests that nurses could assist in improving consent forms so they are readable and understood by patients, and thus, would help in protecting both the patient and the hospital.

For a medical chart to be admissible in court as evidence, several characteristics of charting are required. Some suggestions include that notes be written as soon after the event has occurred, that notes be written by the person involved with the event, and that notes must be written by someone with the "duty of care". This duty of care is described as a professional person on whom the patient relies for their knowledge and skill in medical care (Armstrong, 1988). Charting should be explicit, noting if the patient "appears depressed" and listing the observations that led to this statement. Nursing interventions provided for patient observations, for example, "patient appears nauseated, antiemetic given", convey fact not opinions in charting (Armstrong, 1988). Finally, charting done at the shift's end may contribute to memory lapses, of which the legal implications could be many.

Summary

Patients have the right to make decisions regarding their own care and health care professionals have an obligation to respect that right (Calfee et al., 1991). "A well-informed patient is more likely to trust his doctor and to become a more cooperative, effective partner in his own health care" (Calfee, Caufmann, & Taylor, 1991). The elements of informed consent were reviewed in terms of their description in the literature and related empirical studies. Responsibilities that were described for physicians appeared to be generally well accepted and consistent throughout the literature. Although the nursing responsibilities were well described in the literature, few empirical studies have been conducted to determine what are nurses' perceptions of informed consent. As well, there are contrary opinions of what are nurses' responsibilities. There did not appear to be a consensus of opinion on nursing actions involving witness to informed consent, documentation of informed consent, and providing or explaining information for the purpose of informed consent. When nurses understand the elements and functions of informed consent, they will be better able to assist patients in asking questions and comprehending the information they require to make an informed decision (Fry, 1989).

CHAPTER THREE

Method

A descriptive survey of Alberta nurses was used to (a) identify nurses' knowledge of informed consent, (b) determine the current practice of nurses in informed consent, (c) describe the frequency that nurses encounter informed consent in practice, and (d) determine the relationship of demographic and work-related variables to the knowledge and practices of nurses in informed consent.

Sample

The target population consisted of the 1993 membership list of the Alberta Association of Registered Nurses (AARN). Those nurses who were included in the study met the following inclusion criteria: i) current registration with the AARN, ii) provide direct patient care, iii) hold a position of staff nurse, and/or head nurse, iv) employed in a general hospital or rehabilitation hospital in Alberta. This represented a population of 10,216 nurses; therefore, a sample size of approximately 500 respondents was projected to attain a stratified random sample of five percent of the population. To account for a 30 percent non-response rate, a stratified random sample of 750 nurses was selected by computer. The sample was stratified according to: i) employment status (regular), ii) type of employer (general or rehabilitation hospital), iii) population per registration district in the province of Alberta. Long term care and psychiatric or mental health institutions were not included because of the possibility of special considerations for informed consent situations and for practical purposes related to the number of subjects to be surveyed.

Data Collection Procedures

The sample was accessed through the AARN registrar's office from a complete computerized mailing list of all the registered nurses currently practicing in Alberta who met the inclusion criteria of this study. The AARN arranged for mail distribution of the introductory letter explaining the purpose of the study (Appendix A) and the questionnaire "Nurses' Perceptions of Informed Consent" (Appendix B) to the home addresses of the selected sample. It was explained to the subjects that participation was voluntary, that responses were anonymous, and that the AARN was only distributing the questionnaire and had in no way endorsed the study. Respondents returned the completed questionnaire in a postage-paid, self-addressed return envelope. The AARN automatically mailed a postcard reminder two to three weeks following the initial mailing of the questionnaire (Appendix C).

Instrument

The questionnaire, "Nurses' Perceptions of Informed Consent" (NPIC), was developed based on current clinical experience, previous work with an informal qualitative review of nurses' perceptions of informed consent at the University of Alberta Hospitals, and a review of the literature on informed consent. Questions were based on information in the literature that was identified as being important to the topic of informed consent. The items in the NPIC are related to elements of informed consent in nursing practice and are separated into areas of knowledge, current practice, and demographic data. The first section is comprised of four open-ended questions where nurses are asked for their definition of informed consent, the difference between legal and ethical consent, the role for nurses in informed consent, and their response to an informed consent situation. The second section consists of 15 items which address nurses' knowledge of informed consent related to the types of consent, the elements necessary for consent and information disclosure. The third section comprises 15 items which assess nurses' attitudes towards informed consent by using a Likert scale ranging from strongly agree (1) to strongly disagree (5). The final section includes seven items related to frequency of informed consent encounters and personal demographic characteristics of the respondents.

Content validity of the NPIC was established by a panel of six experts in the area of informed consent (one lawyer, one nurse-lawyer, three doctoral prepared nurses with research and publication expertise in ethics and nursing, and one medical physician with expertise in bioethics) who reviewed the questionnaire for relevance, completeness, and clarity. Minor changes, related to the content, were made as suggested. A Faculty of Nursing professor with expertise in questionnaire design and a peer group of twelve Master of Nursing graduate students then reviewed the questionnaire for clarity and relevance, with minor changes being made only to the format of the questionnaire. The questionnaire was then pilot tested on twelve clinical nurses (who were not included in the final analysis). No further revisions were necessary.

Ethical Considerations

Ethical approval to conduct the study was obtained from the Joint Ethics Review Committee, Faculty of Nursing, University of Alberta (Appendix D). Permission to access potential nursing respondents was obtained from the Executive Director of the Alberta Association of Registered Nurses (Appendix E). The AARN arranged for mail distribution of the randomly selected sample and therefore all replies were anonymous. Participation in the study was voluntary and respondents' consent was implied with the return of the completed questionnaire. The information was treated confidentially and is safely stored in a locked filing cabinet. Any secondary analysis that may be conducted on the information will be done so only after permission has been received from the appropriate ethical review committee.

CHAPTER FOUR

Findings

The purpose of this survey was to elicit information about nurses' knowledge of and practice in informed consent. Information regarding the frequency with which nurses encounter informed consent situations, their definition of informed consent, their knowledge of the types of consent, and their knowledge about information disclosure and patient rights were examined. Nurses' practices in witnessing consent and providing information for the purpose of consent, along with their attitudes regarding nursing roles in informed consent, consent forms, and documentation of consent were obtained. The relationship between demographic and work-related variables with the knowledge and practice of nurses in informed consent was also examined. Data were analyzed using descriptive statistics (SPSSx 4.0, 1990). Frequencies of responses (means, medians, modes, percentages), ranges, and standard deviations were calculated for each item of the Nurses' Perceptions of Informed Consent (NPIC).

Characteristics of the Sample

The respondents consisted of 225 nurses registered in the Province of Alberta in 1993. This provided a survey response rate of 30 percent. Most of the responses were from nurses living in large cities (60.90%). Diploma prepared nurses represented the majority of the respondents (73.30%), with only 49 nurses having completed a baccalaureate degree in nursing (Table 1). The years of nursing practice of the respondents were fairly evenly distributed over a twenty year period with the number of years of practice ranging from 1 year to 40 years (m = 14 years, SD = 8.85 years). Most respondents (93.30%) worked primarily in direct patient care, with the majority working in a general hospital setting (94.70%) versus a rehabilitation hospital setting (1.80%).

Table 1

Distribution of Respondents' Demographic Characteristics

Characteristic	N*	Percent of Responses
Level of Nursing Education		
diploma	165	73.3
baccalaureate	49	21.8
masters	6	2.7
degree other than nursing	4	1.7
missing data	1	0.4
Years of nursing practice		
0-5 years	45	20.00
6-10 years	46	20.44
11-15 years	41	18.22
16-20 years	50	22.22
21-25 years	19	8.44
26-30 years	12	5.33
> 30 years	12	5.33
Place of Residence		
large city (population > 100,000)	137	60.90
city (population < 100,000)	40	17.80
town (population > 3,000)	25	11.10
village (population < 3,000)	6	2.70
other	15	6.70
missing data	2	0.90

(* total N = 225)

Many areas of nursing practice were represented, with 71 nurses working in general medicine, 43 nurses in general surgery , and the next largest group of nurses (26) were employed in the intensive care areas. The reported frequency that nurses were involved in informed consent varies from rare (35.10%) to very frequent (16.00%); however, the majority of nurses were involved in informed consent less than once per week (Table 2).

Table 2
Distribution of Respondents' Nursing Practice Characteristics

Characteristic	N*	Percent of Responses
Place of employment		
General hospital	213	94.7
Rehabilitation hospital	4	1.8
other	8	3.6
Type of nursing position		
Staff nurse	210	93.3
Head nurse	9	4.0
other	6	2.7
Area of nursing practice		
Medicine	71	31.55
Surgery	43	19.11
Intensive Care	26	11.55
Maternal/Newborn	17	7.60
OR/Recovery Room	17	7.60
Emergency	14	6.20
Psychiatry	12	5.30
Gerontology	9	4.00
Ambulatory Care	7	3.10
Pediatrics	7	3.10
Rehabilitation	2	0.88
Frequency involved in informed consent		
rare (less than once/month)	79	35.10
occasional (once/week)	75	33.30
frequent (once a day)	35	15.60
very frequent (more than once/day)	36	16.00

(* total N=225)

Nurses' Knowledge of Informed Consent

Nurses' knowledge of informed consent was obtained in response to open-ended questions asking nurses how they would define "informed consent" and whether or not they thought there was a difference between a legal consent and an ethical consent, multiple choice questions on knowledge areas related to informed consent, and Likert scale responses assessing attitudes towards informed consent. The knowledge areas reviewed included the types of consent, information disclosure, witnessing consent, documentation of consent, and patient rights in informed consent.

Defining Informed Consent

In response to being asked to "define informed consent", nurses' comments were reviewed and categorized according to their similarity in description (Table 3). The most important characteristic of informed consent appeared to be sufficient information (84.88%), which included the necessary elements of information to be disclosed. Fifty-two respondents stated there must be disclosure of information, but they were not specific as to what this should include. Only half (n=122) of the nurses thought that patient understanding of the information was an important part in defining informed consent, and 40 nurses described informed consent as a process. Some nurses (n=35) referred to a consent form or some means of documentation in their definition of informed consent, but very few (n=14) described patient characteristics as a part of defining informed consent.

Table 3
Nurses' Definition of Informed Consent

Descriptor	N*	Percent of Responses
sufficient information	191	84.88
patient understanding of information	122	54.22
disclosure of information	52	23.11
process of consent	40	17.70
consent form/documentation	35	15.50
patient characteristics	14	6.22
no response	6	2.66

(*total N=225)

Disclosure of Information in Informed Consent

In describing disclosure of information, 31 nurses (59.61%) thought that the physician performing the procedure should be responsible for providing the information. Others (34.61%) agreed that information should be provided, but they were nonspecific as to whom should provide it or what the information should include. Three respondents suggested there was a role for written information that could be provided to patients (Table 4).

Table 4
Importance of Disclosure of Information in Informed Consent

Response	N*	Percent of Responses
information should be provided by the physician performing the procedure	31	59.61
information should be provided (nonspecific)	18	34.61
written information should be provided	3	5.76

(* total N=52)

One hundred and twenty two nurses described patient understanding as an important consideration in defining informed consent and they outlined characteristics they thought were associated with this understanding (Table 5). Some nurses (n=29) stated that permission or consent was associated with information disclosure; however, others (n=28) thought that understanding the information was associated with the patient giving permission. Determining patient understanding by having the patient demonstrate his or her knowledge through recall of the information was described by 14 nurses as a method of assessing understanding. Most of the nurses (58.67%) agreed that understanding the disclosed information was necessary in defining informed consent. A few nurses (n=4) however, thought that it was the physician's responsibility to ensure that the patient understands the information.

Table 5
Patient's Understanding the Information Disclosed

Response	N*	Percent of Responses
understanding information disclosed	71	58.67
permission associated with disclosure of information	29	23.96
permission associated with understanding disclosed information	28	23.14
demonstration of understanding through recall of information	14	11.57
physician's responsibility to ensure understanding	4	3.30

(* total N=121)

The Process of Informed Consent

Forty nurses responded that in their perception, informed consent was indeed a process. One of the commonly stated actions they thought may be included in this process was that the information disclosed should be in understandable language or "lay man's terms" (45.00%). Some nurses (n=17) also thought that the ability to ask the physician questions was important. Having time to make a decision before signing the consent form (n=4), and making a decision without undue influence, duress, or coercion (n=8) were also cited as components in the process of informed consent (Table 6).

Table 6
The Process of Informed Consent

Component	N*	Percent of Responses
understandable language	18	45.00
able to ask the physician questions	17	42.50
no undue influence, duress, coercion	8	11.57
time to decide before signing	4	10.00

(* total N=40)

Documentation in Informed Consent

Of the 35 nurses who described documentation in their definition of informed consent, few (17.14%) actually stated that written documentation was necessary. Only seven nurses viewed the consent form as a legal document; however, 27 nurses agreed that the patient's signature was required for permission to perform the test, procedure, or treatment. Witness to the patient's signature was cited as being necessary by eight nurses, while only two nurses felt they should be a witness to the discussion between the physician and the patient (Table 7).

Table 7
Documentation in Informed Consent

Component	N*	Percent of Responses
patient signature is required	27	77.14
consent form is required for permission	9	25.70
witness to signature is required	8	22.85
viewed as a legal document	7	20.00
written documentation necessary	6	17.14
witness physician-patient discussion	2	5.71

(* total N=35)

Perceptions of Ethical and Legal Consent

When asked if nurses thought there was a difference between ethical and legal informed consent, 137 nurses stated there was, 51 responded there wasn't, 17 were unsure, and 20 failed to respond to the question (Table 8).

Table 8

Nurses' Perceptions of Ethical and Legal Consent

Response	N*	Percent of Responses
YES	137	66.82
NO	51	22.66
UNSURE	17	7.55
NO RESPONSE	20	8.88

(* total N=225)

Of those who considered ethical and legal informed consent to be similar, the reason cited was that "if the consent was legal then it must be ethical". Some of the respondents' explanations were unclear (9.8%), and some respondents provided no explanation (21.56%) (Table 9).

Table 9

Nurses' Opinions on the Similarity Between Ethical and Legal Consent

Response	N*	Percent of Responses
if consent "legal" then must be "ethical"	35	68.62
NO similarity	11	21.56
NO (explanation unclear)	5	9.80

(*total N=51)

Of the 137 respondents who stated there was a difference between ethical and legal consent, the most often cited reason was that a legal consent pertained to the signing of the form, whereas, ethical consent pertained to the actual disclosed information and the patient's understanding of it. Some respondents (n=11) described the difference in terms of the legal consent serving to protect the physician, while an ethical consent pertained to what would be "morally correct". Other respondents (n=23) were in agreement with the idea that the consent is to protect the physician however, they also thought ethical consent served to protect the patient's rights (Table 10).

Table 10

Nurses' Opinions on the Difference Between Ethical and Legal Consent

Response	N*	Percent of Responses
legal pertains to signing the form ethical pertains to information & patient understanding	58	42.33
legal protects the physician ethical pertains to moral correctness	29	21.16
legal protects the physician ethical protects the patients' rights	23	16.78
YES (only response)	10	7.29
YES (explanation unclear)	17	12.40

(* total N=137)

Types of Consent

Examples of consent situations were provided and 217 respondents (96.44%) recognized that signing a form to permit a test, procedure, or treatment was a valid form of consent. Verbal agreement from a patient was recognized by 82.22%, and a patient's physical indication of agreement, or implied consent, was recognized by 76.88%.

However, one-half of the respondents (n=114) also thought that a patient submitting to a test, procedure, or treatment based on a physician's recommendation, could be seen as valid consent (Table 11).

Table 11
Nurses' Recognition of the Types of Consent

Types of Consent	N*	Percent of Responses
signing a form to permit the test, procedure, or treatment	217	96.44
verbal agreement	185	82.22
implied consent	173	76.88
physician recommendation	114	50.66

(* total N=225)

Patient Characteristics Necessary in Informed Consent

Patient characteristics were described as an important aspect of informed consent by fourteen nurses responding to the open-ended question to define informed consent. All of these respondents agreed that patients must be mentally competent. Only four nurses thought that patients must be of legal age, two nurses thought they must be able to voluntarily consent, and two nurses thought patients must not be under the influence of drugs (Table 12).

Table 12
Patient Characteristics Necessary in Informed Consent

Characteristic	N*	Percent of Responses
mental capacity/ competent	14	100.00
legal age	4	28.57
voluntary	2	14.28
not under the influence of drugs	2	14.28

(* total N=14)

In examination of the multiple choice items regarding patient characteristics, each response was individually reviewed. The majority of nurse respondents agreed that being able to understand the information disclosed (n=222), having received sufficient information (n=217), being mentally competent (n=210), and being of legal age (n=185), were necessary in informed consent. No undue influence appears to be of somewhat lesser importance (n=171), and the ability to speak English was thought to be necessary in informed consent by very few nurses (n=37) (Table 13).

Table 13

Nurses' Knowledge of Patient Characteristics Necessary in Informed Consent

Characteristic	N*	Percent of Responses
able to understand disclosed information	222	98.66
receipt of sufficient information	217	96.44
mental competence	210	93.33
legal age	185	82.22
no undue influence	171	76.00
able to speak English	37	16.44

(* total N=225)

Elements of Disclosed Information

In response to the open-ended question on defining informed consent, many respondents stated that sufficient information was important in informed consent and they included a description of the elements required in this "sufficient information" (Table 14). Cited most often were outlining the risks and benefits (82.72%) and the description of the test, procedure, or treatment (74.68%). Less often stated were the need to know the complications that may be related to the test, procedure, or treatment (32.46%), the alternatives to the test, procedure, or treatment (25.65%), and the outcomes or anticipated recovery (22.87%). Only 29 nurses declared a need to know the reason for the test, procedure, or treatment to be included in the information disclosed.

Table 14

Elements of the Information Disclosed that are Important in Informed Consent

Elements	N*	Percent of Responses
risks & benefits of test, procedure, or treatment	158	82.72
description of test, procedure, or treatment	143	74.86
complications related to test, procedure, or treatment	62	32.46
alternatives to test, procedure, or treatment	49	25.65
outcomes/recovery related to test, procedure, or treatment	43	22.87
reason for test, procedure, or treatment	29	15.18

(*total N=191)

In the multiple choice questions, closer exploration of the specifics of the information that should be disclosed for the purpose of informed consent was conducted. The responses were reviewed individually and the findings indicated that the majority of nurses (n=222) agreed that knowing the nature of the test, procedure, or treatment was important. Important elements identified were possible complications (n=217), associated material risks (n=208), the knowledge of who will be performing the test, procedure, or treatment (n=206), and the alternatives to the test, procedure, or treatment (n=202). The outcome if patients were to decide not to have the test, procedure, or treatment (n=191), the probability of the procedure or treatment's success (n=190), and the desire or need to know the diagnosis or nature of the illness (n=186) were perceived as somewhat less important (Table 15).

Table 15

Nurses' Perceptions of the Information Necessary to Achieve Informed Consent

Elements	N*	Percent of Responses
nature of test, procedure, treatment	222	98.66
possible complications	217	96.44
associated material risks	208	92.44
who will be performing test, procedure, or treatment	206	91.55
alternatives to test, procedure, or treatment	202	89.77
outcome without test, procedure, or treatment	191	84.88
probability of success of test, procedure, or treatment	190	84.44
diagnosis/ nature of illness	186	82.66

(* total N=225)

Responsibility for Disclosure of Information

A significant aspect of information disclosure is not only the kind of information that is required by the patient, but who is presenting the information to the patient. In review of the individual responses to the multiple choice question, most responses indicated that the responsibility for disclosure of information was with the physician who was performing the procedure (Table 16).

Table 16

Responsibility for Disclosure of Information in Informed Consent

Responsible Person	N*	Percent of Responses
physician performing test, procedure, or treatment	219	97.76
delegated medical resident	71	31.69
nurse	25	11.16
any physician	14	6.25

(* total N=224)

The act of obtaining informed consent appeared to produce a variety of responses from nurses. Overall, 90.22% of the respondents thought that making sure the patient understood the information was the most important part of obtaining informed consent (Table 17). In the multiple choice question, the most frequently select combination of responses included getting the patient's signature on the form, giving the patient the information, and making sure the patient understood the information (49.50%).

Table 17

Nurses' Perceptions of the Meaning of "Obtaining Informed Consent"

Meaning	N*	Percent of Responses
making sure the patient understands the information	203	90.22
giving the patient information to decide	159	70.66
getting the patient's signature on the form	141	62.66

(* total N=225)

Witness to Informed Consent

In examining the role of witness to informed consent, the response of observing the patient sign his or her name was selected by 107 respondents, and agreeing that the patient understood the information that had been disclosed, was selected by 106 respondents. Sixty-three nurses agreed that listening to the physician explain the test, procedure, or treatment was important and another 59 nurses perceived that ensuring correct information was given is important in the role of witness (Table 18). The most frequent response to the meaning of witness to informed consent was to observe the patient sign the consent form (47.55%), while the most frequently chosen combination of responses to the role of witness included observing the patient sign the form, agreeing that the patient understands the information, listening to the physician's explanation, and agreeing that the information was correct (16.5%).

Table 18

Nurses' Perceptions of Witnessing Consent

Witnessing	N*	Percent of Responses
observing patient sign the form	107	47.55
agree that patient understands the disclosed information	106	47.11
listen to physician's explanation	63	28.00
agree that information disclosed is correct	58	25.77

(*total N=225)

In assessing nurses' knowledge of who can witness a consent, the most frequent response chosen was the nurse who listened to the physician's explanation (71.81%), while the physician performing the test, procedure, or treatment was the next response chosen (63.63%). Few respondents saw hospital employees (17.72%) or relatives of the patient (16.81%) as persons who could witness a consent (Table 19).

Table 19

Nurses' Knowledge of Who Can Witness Consent for a Medical or Surgical Test, Procedure, or Treatment

Person	N*	Percent of Responses
nurse who listened to physician's explanation	158	71.81
physician performing test, procedure, or treatment	140	63.63
any nurse	116	52.72
any physician	98	44.54
any hospital employee	39	17.72
relative of the patient	37	16.81

(* total N=220)

Nurses' Perceptions of Patients' Rights

Nurses' perceptions of patients' rights are outlined in Table 20. In examination of all the possible choices, the majority of nurses (67.40%) agreed that receiving sufficient information to decide, being able to change or withdraw a decision, and being able to refuse a test, procedure, or treatment were all important rights. Reviewing the single items indicated that nurses thought that sufficient information (n=220), being able to change or withdraw a decision (n=214), and the ability to refuse a test, procedure, or treatment (n=217) were important patient rights. Some nurses (n=61) recognized the patient's right to waive or refuse information but still make a decision, and very few nurses (n=3) thought the patient should receive only that information the physician felt was necessary to make a decision.

Table 20

Patients' Rights in Informed Consent

Rights	N*	Percent of Responses
receive sufficient information	220	97.77
right to refuse test, procedure, or treatment	217	96.44
right to change decision or withdraw from treatment	214	95.11
right to refuse/waive information	61	27.11
receive only that information the physician feels is necessary	3	1.30

(* total N=225)

Nurses' Opinions on Written Informed Consent

In review of the responses regarding nurses' opinions of the value of written informed consent, most nurses agreed this helped patients maintain their right to decide (90.13%). About one-half of the nurses (n=118) agreed that written informed consent protected physicians from being sued, protected nurses and the hospital from liability (48.87%), and that informed consent could assist the patient in making the best decision for him/herself (45.29%) (Table 21). The most frequent combination of responses to this multiple choice question included protecting the physician, protecting nurses and hospitals from liability, assisting patients to maintain their right to decide, and assisting patients in making the best decision (21.30%).

Table 21
Nurses' Perceptions of the Value of Written Informed Consent

Perception	N*	Percent of Responses
assists the patient to maintain their right to decide	201	90.13
protects the physician from being sued	118	52.91
protects nurses/hospitals from liability	109	48.87
assists patient in making a decision	101	45.29

(* total N=223)

The value of the consent form was described most frequently (n=193) as being evidence of some kind of discussion about a test, procedure, or treatment, and 167 respondents agreed it was evidence of "informed consent " (Table 22). Some nurses thought that the consent form could prevent the physician from being sued and that the form eliminated liability of the hospital. Only one nurse thought that there was no value to a consent form. The most frequently chosen combination of these responses included the consent form as evidence of informed consent and as evidence of some form of discussion about a test, procedure, or treatment (42.90%).

Table 22
Nurses' Perceptions of the Value of a Consent Form

Perception	N*	Percent of Responses
evidence of discussion about test, procedure, or treatment	193	86.16
evidence of informed consent	167	74.55
prevent physician from being sued	50	22.32
eliminate hospital liability	34	15.17
no value	1	0.40

(* total N=224)

In review of what information should be included on the consent form, many nurses (n=94) felt that the name of the test, procedure, or treatment, the name of the physician performing it, the patient's signature, the physician's signature , and the witness's signature were important. Table 23 depicts the breakdown of the individual items to include on a consent form.

Table 23

Information That Should Be Included on a Consent Form

Information Element	N*	Percent of Responses
name of test, procedure, or treatment	224	100.00
patient's signature	223	99.55
name of the physician performing the test, procedure, or treatment	219	98.20
witness's signature	209	93.30
physician's signature	183	81.33
risks involved	80	35.71
expected benefit/ prognosis	51	22.76

(* total N=224)

In summary, the respondents consisted largely of diploma prepared nurses, living in a large city and working primarily in direct patient care in a general hospital. These nurses generally agreed that for consent to be informed, the patient should receive sufficient information provided by the physician performing the test, procedure, or treatment which should include information about the nature of the test, procedure, or treatment, as well as the risks and benefits. Of lesser importance appeared to be the information related to complications of the test, procedure, or treatment, the alternatives, and the outcomes or anticipated recovery. Very few nurses described a need to know the reason for the test, procedure, or treatment. Most nurses thought that patient 's understanding of the information was important and that mental competence and being of legal age were also necessary for consent to be informed.

Nurses mainly agreed that written informed consent was a tool to assist patients maintain their right to decide, but many nurses still thought it was to protect physicians, nurses, and hospitals from liability. The concept of a witness to informed consent was thought to be observing a patient sign his or her name by only one-half of the respondents, and a number of nurses thought they should witness the discussion prior to signing as a witness and ensure that the information was correct. Most nurses thought that the witness should be the nurse who listened to the physician's explanation but very few nurses recognized that other hospital employees or the patient's relatives could act as witnesses to consent. The majority of nurses did agree that patients have the right to receive information, make and/or change a decision, and to refuse a test, procedure, or treatment.

Nursing Practices in Informed Consent

Nursing practices in informed consent were solicited through an open-ended question asking respondents if they felt "nurses should have a role in informed consent", through multiple choice questions, and through assessment of attitudes toward informed consent based on responses to questions using a Likert scale. Practices in informed consent were examined in the areas of disclosure of information, witness to consent, nursing responsibilities in informed consent, and documentation of informed consent.

Perceptions of Nurses' Role in Informed Consent

The majority of nurse respondents (71.55%) agreed they do have a role in informed consent, while 17.33% thought that they did not, and 2.22% failed to respond (Table 24).

Table 24

Do Nurses Have a Role in Informed Consent?

Response	N*	Percent of Responses
YES	161	71.55
NO	39	17.33
NO RESPONSE	5	2.22

(* total N=225)

The nurses who thought they had no role in informed consent attributed this to the fact they thought the physician or person performing the procedure should be responsible for informed consent (92.30%). However, despite responding that nurses should have no role in informed consent, many of the nurses went on to describe nursing practices in informed consent. These included witness to a patient's signature (n=5), reinforcing information (n=4), verifying the patient's understanding (n=2), and recalling the physician to talk with the patient if they felt the patient did not understand (n=2) (Table 25).

Table 25

Nurses' Opinions of No Nursing Role in Informed Consent

Role	N	Percent of Responses
physician's responsibility	36	92.30
Suggested roles for nurses, despite responding there was "NO ROLE"		
only responsibility is witness	*5*	*12.80*
reinforce information	*4*	*10.25*
verify understanding	*2*	*5.12*
explain nursing care	*2*	*5.12*
recall physician to talk to patient	*2*	*5.12*

The stated descriptions of nursing practice in informed consent are outlined in Table 26. The most often cited practices included assessing the patient's understanding of the information disclosed (37.88%), answering the patient's questions (13.66%), reinforcing the information disclosed by the physician (11.18%), clarifying the information disclosed by the physician (17.39%), witnessing the patient's signature (10.55%), clerical duties such as ensuring that the consent form is correctly completed (12.42%), and acting as a patient advocate (21.73%). Facilitation of the patient-physician relationship was cited by 14.28% of the respondents, while some nurses (11.42%) thought that they should ensure that the patient has all the information necessary to make a decision.

Table 26

Nurses' Descriptions of Nursing Practice in Informed Consent

Nursing Practice	N*	Percent of Responses
assess patient's understanding of information	61	37.88
act as patient advocate	35	21.73
nurse can clarify the disclosed information	28	17.39
nurse can answer the patient's questions	22	13.66
nurse ensures form correctly completed	20	12.42
nurse can reinforce information disclosed	18	11.18
act as witness to signature	17	10.55
nurse ensures patient questions are answered by physician	13	8.07
nurse ensures patient has sufficient information	12	7.45
nurse can provide additional information	8	4.96
nurse encourages patient to ask questions	7	4.34
nurse can inform patient about the right to informed consent	7	4.34
nurse has role only if procedure is related to nursing	7	4.34
nurse should be knowledgeable about test, procedure, or treatment	6	3.72
nurse cannot provide the initial information required for informed consent	5	3.10
nurse supports patient in their decision	2	1.24
unclear descriptions	22	13.66

(* total N=161)

A few respondents (n=9) stated there was a patient advocate role in informed consent; however, they failed to describe what this role involved. Descriptions of the advocate role as stated by other respondents included ensuring the patient's understanding of the information (n=14), clarifying the information (n=5), answering the patient's questions (n=2), recalling the physician to talk with the patient if it appears he or she doesn't understand the information (n=7), and telling the patient of their right to an informed consent (n=5) (Table 27). As previously noted, many of these practices described as patient advocate were also cited as roles for nurses in informed consent, although not specifically described as "advocate" roles.

Table 27

Nurses' Perceptions of the Patient Advocate Role for Nurses in Informed Consent

Advocate Role	N*	Percent of Responses
ensure patient understanding of the information	14	40.00
recall physician to talk with patient if it appears the patient doesn't understand the information	7	20.00
clarify the information	5	14.28
facilitate patient-physician relationship	5	14.28
tell patients of their right to an informed consent	5	14.28
ensure patient has all the information needed to make a decision	4	11.42
answer the patient's questions	2	5.71
no description of advocate role despite stating the advocate role existed	9	25.71

(* total N=35)

In review of nurses' knowledge of their role and practice in informed consent through the multiple choice question selections, nurses perceived their role in informed consent as assisting the patient in understanding the information (n=208) and witnessing the patient's signature on the consent form (n=189), while a very small minority thought they had no role (n=3). A few nurses (29.01%) thought they may provide information related to risks and complications (Table 28). The most frequently selected combination of responses included ensuring the patient understands the information, ensuring the patient has signed the consent form, and witnessing the patient sign the consent form (31.70%). The next most common combined response included making sure the patient understands the information and witnessing the patient sign the consent form (25.90%).

Table 28

Nurses' Perceptions of a Nursing Role in Informed Consent

Role	N*	Percent of Responses
assist the patient to understand the information disclosed	208	92.85
witness patient signature	189	84.37
get the patient's signature on the form (not acting as witness)	133	59.37
provide information related to risks and complications	65	29.01
no role	3	1.33

(* total N=224)

Nurses' opinions of their responsibilities in informed consent are outlined in Table 29. The single item most often selected was ensuring that patients understood what they were consenting to (95.53%) and then ensuring the consent form was properly completed (95.10%). Of slightly lesser importance were ensuring the patient had signed the consent form (78.57%) and ensuring the physician had given the patient all the information (65.62%). Very few nurses (n=6) agreed they should recommend a specific test, procedure, or treatment. A number of respondents (n=110) thought they had several responsibilities in informed consent. The most frequently chosen (49.10%) combined response included making sure the consent form was properly completed, making sure the patient had signed the consent form, making sure the patient had understood what he or she was consenting for, and making sure the physician had given the patient all the information.

Table 29

Nurses' Opinions of Nursing Responsibilities in Informed Consent

Responsibility	N*	Percent of Responses
ensure patient understands what he or she has consented for	214	95.53
ensure consent form properly completed	205	91.50
ensure patient has signed consent form	176	78.57
ensure physician has given the patient all the information	147	65.62
making a recommendation for a specific test, procedure, or treatment	6	2.67

(* total N=224)

In response to the action nurses should undertake when they think that the patient doesn't understand the information, most nurses (96.00%) perceived they should have the physician return and explain the information to the patient again. Some nurses (n=131) thought they could explain the information in terms the patient could understand, but very few (n=28) thought they should provide the patient more information about risks and complications (Table 30). The most frequently chosen (44.64%) combination of responses included the actions of having the physician return to explain the information and having nurses explain the information in terms the patient could understand

Table 30

Nursing Responsibilities When the Patient Doesn't Understand the Information

Responsibilities	N*	Percent of Responses
recall physician to explain further	216	96.00
explain information in understandable terms	131	58.22
provide additional information about risks and complications	28	12.44

(* total N=225)

Nurses' Opinions on Documentation of Informed Consent

In assessing nurses' opinions and their practices in informed consent through the Likert scale responses, the majority of nurses disagreed (mean=4.15, SD=0.75) that the most important part of consent was signing the form, although 72.50% agreed that it was necessary to document informed consent with a consent form. The documenting of informed consent appeared to be an uncertain topic, with only one-half (n=121) of the nurses agreeing that documenting informed consent was the physician's responsibility, while 56 nurses disagreed, and 44 nurses were not sure whose responsibility it was. Nurses also did not appear to have a consistent practice in regards to whether or not they should be present during the discussion between the physician and the patient for the purpose of informed consent. There appeared to be an almost equal number of respondents who agreed (n=92) and disagreed (n=108) with this practice (Table 31).

Table 31

Nurses' Opinions on the Documentation of Informed Consent

Statement	N*					Mean	SD
	strongly agree	agree	not sure	disagree	strongly disagree		
most important part of consent is signing the form (N*=223)	2	11	3	143	64	4.1	0.75
necessary to document consent with the consent form (N*=222)	41	120	38	21	2	2.2	0.88
documentation of consent is the physician's responsibility (N*=221)	40	81	44	55	1	2.5	1.07
nurses need to be present during the patient-physician discussion (N*=222)	22	70	22	88	20	3.1	1.21

Nurses' Opinions of Providing Information for the Purpose of Obtaining Informed Consent

In looking at information disclosure practices, the majority of nurses agreed that the physician performing the procedure is legally responsible for information disclosure (n=198, mean=1.65, SD=0.76). Some nurses (n=113) thought they could give patients more information only if it had already been discussed by the physician; however, 94 nurses thought they could provide additional information about risks and complications if they perceived the patient was inadequately informed. Some nurses agreed (n=136, mean=2.58, SD=1.26) that a role in informed consent was to clarify the information provided by the physician; however, 66 nurses disagreed and 21 nurses were not sure that this was a nursing practice (Table 32).

Table 32
Nurses' Opinions on Providing Information to Patients for the Purpose of Informed Consent

Statement	N*					Mean	SD
	strongly agree	agree	not sure	disagree	strongly disagree		
physician performing procedure is legally responsible for information disclosure (N*=225)	110	88	21	6	0	1.65	0.76
nurses can provide additional information about risks & complications if they think the patient is inadequately informed (N*=223)	22	72	32	66	31	3.05	1.25
nurses can give information if it has been discussed by the physician (N*=223)	24	89	11	78	21	2.92	1.25
nurses' role in informed consent is to clarify information disclosed by the physician (N*=223)	44	92	21	46	20	2.58	1.26

Nurses' Perceptions of the Process of Informed Consent

Nurses generally perceived the most important part of informed consent as being the discussion between the physician and the patient, with 91.10% of nurses in agreement. The majority of nurses (n=180) strongly agreed that patients can ask questions after the consent form has been signed. Almost all of the nurses (91.10%) agreed that informed consent is a process of shared decision-making and very few nurses were not sure (n=6) or disagreed (n=14) with this practice (Table 33).

Table 33

Nurses' Perceptions of the "Process" of Informed Consent

Statement	N*					Mean	SD
	strongly agree	agree	not sure	disagree	strongly disagree		
informed consent is a process of shared decision-making (N*=225)	99	106	6	10	4	1.73	0.86
most important part of consent is discussion between patient & physician (N*=225)	117	85	8	4	1	1.56	0.69
patient can ask questions after consent form has been signed (N*=224)	180	43	1	0	0	1.20	0.41

Nursing Actions in Response to Case Example

Practices in informed consent can be further illustrated with the nurses' responses to a case example presented in the questionnaire (NPIC) which describes the consent situation of a patient requiring a surgical procedure. Nurses were asked to respond as to how they would improve, if necessary, the patient situation that was described. The results are presented in Table 33. The most frequently described actions included the nurse notifying the physician of the patient's need for more information and arranging for further discussion (n=110), finding out why the patient is upset (n=87), and clarifying or reinforcing the disclosed information (n=45). Few nurses in this situation described assessing the patient's understanding of the procedure (n=35) and asking the patient if they had any questions about the procedure (n=27). Only 22 respondents thought they should be able to answer the patient's questions and 16 respondents thought they should explain more about the procedure (Table 34).

Thus, nurses' practices in informed consent were assessed from a variety of sources. Generally, the nurse respondents indicated that there is a role for nurses in informed consent. Those nurses who disagreed with this view did so because they stated that informed consent was solely the responsibility of the physician.

The practices of nurses in informed consent appeared to be largely related to the patient's understanding of the information with nurses answering questions, clarifying information, reinforcing information, and notifying the physician if they thought the patient required further explanation. There was almost unanimous agreement that the responsibility for information disclosure was the physician's responsibility. Regardless of whether or not the information had been discussed by the physician first, nurses were inconsistent in their practices of giving the patient additional information about risks and complications if they thought the patient was inadequately informed. Nurses did

Table 34

Descriptors of Nursing Actions in Response to Case Example

Nursing Action	N*	Percent of Responses
notify physician of patient's need for more information, arrange further discussion	110	48.88
find out why the patient is upset	87	38.66
can clarify/reinforce information	45	20.00
assess patient's understanding of procedure	35	15.55
ask patient if have any questions (in the physician's presence)	32	14.22
ask patient if they have any questions (not in physician's presence)	27	12.00
patient may need time to decide before signing consent form	25	11.11
nurse should be able to answer patient's questions	22	9.77
nurse allow/encourage patient to verbalize emotions	18	8.00
nurse should explain more about procedure	16	7.11
assist patient to form questions to ask the physician	8	3.55
nurse ask the physician questions to facilitate discussion	8	3.55
nurse can tell patient about their right to an informed consent	6	2.66
nurse should document the situation	6	2.66
nurse could provide additional written/ audiovisual information	5	2.22
no response	6	2.66
unclear explanation	3	1.33

(* total N=225)

however, agree that the most important part of the process of informed consent was the discussion between the patient and the physician.

Nurses appeared to be inconsistent in their opinion of whether they should be present during the discussion between the patient and physician for the specific purpose of documentation of the informed consent, as well, the responsibility for this documentation of informed consent was also uncertain. Nurses were not in agreement as to whether documentation was the responsibility of physicians or nurses. Witnessing patients' signatures and clerical duties such as making sure the consent form was completed properly, were less often cited.

Nursing Knowledge and Practice in Informed Consent Related to Demographic Characteristics of Nurse Respondents

Since variables like educational background, the area of employment, the area of practice in nursing, the number of years of practice, and the frequency with which one is involved in informed consent could have an influence on how nurses respond to the survey items, analysis was conducted to examine the association between nurses' knowledge of and practice in informed consent. The Pearson product-moment correlation was conducted to assess the relationship between nurses' knowledge and practice and their personal demographic characteristics.

Relationships Between Knowledge of Informed Consent and Personal Characteristics

Tables 35 and 36 illustrate those relationships that were found to be statistically significant at the $p=.05$ level. Analysis showed no statistically significant relationship between any of the knowledge responses and the type of nursing position (staff or head nurse). Statistically significant relationships, although very weak, were found among some of the personal demographic characteristics. Identification of who could act as witness to informed consent was associated with the level of education of the respondents (r=0.15, p=0.014). Most diploma prepared nurses identified a witness as the physician who will perform the test, procedure, or treatment, and the nurse who listened to the discussion. A statistically significant relationship existed between the place of employment and the meaning of witnessing a consent (r=0.12, p=0.04), with more staff nurses describing the meaning of witnessing consent as observing the patient sign his or her name.

A negative relationship was demonstrated between the frequency nurses were involved with informed consent and the action that is taken by nurses if they felt patients did not understand the information (r=-0.12, p=0.38). Nurses who were frequently involved with informed consent (e.g.., once or more than once a day) were more likely to recall the physician to further explain the information or to answer the patient's questions. A statistically significant negative relationship existed between the area of nursing practice and the ability to identify the different types of consent (r=0.12, p=0.04). Nurses from areas *other* than general medicine appear more likely to identify implied consent, verbal consent, a patient submitting to a test, procedure, or treatment because the physician recommends it, and a patient signing a consent form, as valid forms of consent. The area of nursing practice was also seen in association with the elements of information that are necessary for a consent to be informed (r=0.13, p=0.26). Nurses practicing in general medicine appeared to identify the need to know information about the test, procedure, or treatment, and making the decision based on personal choice, as necessary to achieve informed consent. Lastly, nurses practicing in general medicine were more inclined to view written informed consent as protecting the physician from getting sued, protecting

Table 35

Significant Relationships Between Knowledge of Informed Consent and Personal Demographic Characteristics

Knowledge Items	Frequency Involved in Consent		Level of Education		Place of Employment		Nursing Position	
	r	p	r	p	r	p	r	p
witnessing consent	-2.1	0.001	0.03	0.304	0.12	0.04 *	-0.07	0.140
who can witness	0.19	0.002	0.15	0.14 *	0.02	0.413	0.01	0.433
action taken by RN if the patient doesn't understand	-0.12	0.038 *	0.01	0.456	0.01	0.116	-0.20	0.392

* $p < .05$.

nurses and hospitals from liability, helping the patient maintain their right to decide, and helping the patient to make the best decision for him or herself ($r=0.13$, $p=0.025$).

A negative relationship existed between the years of nursing practice and identification of patients' rights ($r=-0.13$, $p=0.05$); thus, nurses with fewer years of nursing practice were more likely to identify the receipt of sufficient information necessary to make a decision, the right to refuse information, and the right to change or withdraw a decision, as patient rights in informed consent. A negative relationship also existed between patient rights and nurses' place of residence ($r=-0.12$, $p=0.04$). Nurses who come from areas other than a large city (population over 100,000) were more likely to identify the right to include the receipt of sufficient information necessary to decide, the right to refuse information, and the right to change or withdraw a decision, as patient's rights in informed consent.

A negative relationship exists between the years of nursing practice and the type of information the nurses thought should be included on the consent form ($r=-0.12$, $p=0.33$). The fewer the years of nursing practice, the more likely nurses would identify the name of the test, procedure, or treatment, the name of the physician performing the test, procedure, or treatment, the patient's signature, the physician's signature, and a witness's signature, as information to be included on a consent form.

Table 36
Significant Relationships Between Knowledge of Informed Consent and Nursing Practice Characteristics

Knowledge Items	Area of Nursing Practice		Years of Nursing Practice		Residence	
	r	p	r	p	r	p
types of consent	-0.12	0.04 *	0.06	0.192	-0.10	0.062
information elements	0.13	0.026 *	-0.01	0.437	0.11	0.051 *
action taken by RN if the patient doesn't understand	0.04	0.266	0.12	0.046 *	0.08	0.108
value of written consent	0.13	0.025 *	0.08	0.130	0.06	0.203
information on consent form	0.05	0.219	-0.12	0.033 *	-0.02	0.489
patient rights	0.07	0.156	-0.13	0.028 *	-0.12	0.41

* p <.05.

Relationship Between Nurses' Practices in Informed Consent and Personal Characteristics

Table 37 depicts some of the associations found between the nurse respondents' personal characteristics and the nursing practices in informed consent. The location of residence of the nurse respondents was found to be associated with the identified responsibilities of nurses in informed consent (r=0.12, p=0.034). Nurses who lived in large cities (population greater than 100,000) are more likely to identify their responsibilities in informed consent to include making sure the consent was properly signed, making sure the patient signed the consent form, making sure the patient understands what he or she is consenting for, and making sure the physician has given all the information that is needed for consent. There was a relationship between the frequency involved in informed consent and the role of clarifying information (r=0.14, p=0.021), indicating that the more often nurses are involved in informed consent, the more likely they are to see clarifying information as a role for nurses in informed consent.

The level of education of nurses was associated with how important nurses feel it is to document informed consent (r=0.11, p=0.047). Diploma prepared nurses were inclined to agree that documenting informed consent with a consent form is necessary. An inverse or negative relationship was seen between the level of education of nurses and their provision of support to patients in their decision-making, with less support occurring amongst diploma prepared nurses.

The place of employment, most frequently being in a general hospital, appears to have a rather weak but statistically significant relationship with the responsibility for documentation of informed consent (r=0.13, p=0.023). Nurses working in a general hospital were more inclined to agree that the physician should be responsible for documenting informed consent. Another statistically significant inverse relationship was seen between place of employment and the perception that nurses could give patients additional information about risks and complications if they felt the patient was inadequately informed (r=-0.14, p=0.015). The mean response for this question was 3.054 or "not sure"; however, 42.14% of the nurses agreed versus 39.49% who disagreed. Therefore, the trend may be that general hospital nurses were slightly less likely to give the patient more information about risks and complications if they felt the patient was inadequately informed.

The position of head or staff nurse appeared to have an inverse relationship with the responsibility for information disclosure being the physician performing the procedure (r=-0.12, p=0.032) and that nurses can tell the patient they have the right to refuse to undergo a test, procedure, or treatment (r=-0.11, p=0.045). It appears from this, that head nurses were more likely to respond that physicians are responsible for information disclosure, and that nurses can tell the patient that they have the right to refuse a test, procedure, or treatment.

Some of the nursing practice items found in informed consent were associated with the nurse respondents demographic variables (Table 38). The area of nursing practice was found to be related to the nurses' role of clarifying information ($r=0.11$, $p=0.047$). Nurses in general medicine were more inclined to clarify information provided by the physician for the purpose of informed consent. There was a weak relationship between the years of nursing practice and whether nurses should support patients in their decision ($r=0.13$, $p=0.03$) and if they feel patients are capable of understanding information about the test, procedure, or treatment ($r=0.13$, $p=0.023$). Nurses who have been in practice longer appeared to think a nursing role is to support patients in their decisions, and they tend to believe that patients do have the potential for understanding the information related to the test, procedure, or treatment.

An inverse relationship was shown to exist between the location of residence and the belief that a nursing role is to provide additional information about risks and complications if they feel the patient is inadequately informed ($r=-0.14$, $p=0.019$). Again this poses a problem as the mean score for this question was 3.054 or "not sure" (42.14% agreed versus 39.49% who disagreed). Therefore, the trend may be that nurses who live in areas other than large cities were slightly more likely to see a nursing role that includes providing information to patients about risks and complications if they felt the patients were inadequately informed. There was a small non-significant negative trend between nursing position and whether or not nurses think patients are capable of understanding the information ($r=o-0.11$, $p=0.052$). It appears that head nurses are more likely to agree that patients can understand information given about the test, procedure, or treatment.

Table 37
Significant Relationships Between Nursing Practices in Informed Consent and Personal Demographic Characteristics

Nursing Practice	Frequency Involved in Consent		Level of Education		Place of Employment		Nursing Position	
	r	p	r	p	r	p	r	p
Dr performing procedure responsible for information disclosure	-0.00	0.486	0.06	0.184	0.05	0.194	-0.12	0.032 *
RN clarify information	0.14	0.021 *	0.03	0.350	-0.05	0.226	-0.00	0.492
RN give information on risks/ complications	0.19	0.002	-0.05	0.235	-0.15	0.015 *	0.05	0.244
RN should support patient decision	0.00	0.439	-0.15	0.014 *	-0.09	0.090	-0.90	0.080
RN can tell patient they have the right to refuse	0.04	0.272	-0.11	0.057	-0.03	0.340	-0.11	0.045*
Documentation is important	-0.2	0.369	0.11	0.047 *	0.01	0.427	0.07	0.168
Documentation is the Dr's responsibility	-0.01	0.447	-0.01	0.468	0.13	0.023 *	0.05	0.206

* $p < .05$.

The years of nursing practice were seen to be weakly associated with a number of nursing practices. A statistically significant relationship existed between the number of years of nursing practice and the action nurses take when they feel patients do not understand the information ($r=0.11$, $p=0.046$). The more years of nursing practice the more likely nurses were to explain the information in terms the patient can understand, and call the physician back to further repeat the information and answer questions if necessary.

Consequently, nurses' knowledge of informed consent does have some relationship with the respondents' demographic and work-related variables. The more often nurses were involved with informed consent, the greater the likelihood they would notify the physician to further explain the information if the patient did not appear to understand. Diploma prepared nurses were more inclined to identify the persons who could act as witness to informed consent to be the physician performing the procedure, or the nurse who listened to the procedure. Nurses working in a general hospital were more likely to describe the act of witness to informed consent as observing the patient sign his or her name to the form.

Table 38
Significant Relationships Between Knowledge of Informed Consent and Nursing Practice Characteristics

Knowledge Items	Area of Nursing Practice		Years of Nursing Practice		Residence	
	r	p	r	p	r	p
RN can clarify information	0.11	0.047 *	-0.08	0.133	0.02	0.382
RN can give information on risks/ complications	-0.70	0.165	-0.00	0.478	-0.14	0.019 *
RN support patient decision	0.03	0.347	0.13	0.030 *	0.03	0.340
patient can understand the information	-0.07	0.460	0.14	0.023 *	0.07	0.146

* $p < .05$.

Nurses working in general medical areas were likely to identify the need to know information about the test, procedure, or treatment and patient's personal choice as determinants of informed consent. These nurses however, were less likely to recognize implied consent, verbal consent, the patient signing the consent form, and the patient submitting to a test, procedure, or treatment based on the physicians' recommendation, as valid types of consent. Nurses from areas of general medicine were more likely to think that written informed consent was to protect the physician, the nurse, and the hospital from liability. Nurses with fewer years of nursing practice and/or who come from areas other than a large city were more likely to identify the receipt of information to decide, the right to refuse information, and the right to change or withdraw a decision, as recognized patient rights in informed consent.

In nursing practice, the more often nurses were involved in informed consent, the more likely they saw clarifying as a nursing role in informed consent. Diploma prepared nurses were more inclined to see written documentation of informed consent as important; however, they are less likely to support a patient in his or her decision. Nurses in a general hospital were less likely to give additional information about risks and complications if they felt the patient was not adequately informed. Nurses employed in a general hospital, in a head nurse position, were more inclined to agree that the physician is responsible for informed consent, and head nurses were more likely to tell patients they have the right to refuse a test, procedure, or treatment. Nurses who work in the general medical areas were more inclined to clarify information provided by the physician for the purpose of informed consent.

The more years of nursing practice, the more likely that nurses believed that patients are capable of understanding information for the purpose of informed consent. Nurses with more years of nursing practice are also more inclined to explain the information in terms the patient can understand, and are more likely to support patients in the treatment decisions they make.

CHAPTER 5

Discussion of Findings

This study was designed to describe nurses' perceptions of informed consent. Specific areas of informed consent that were assessed included nurses' knowledge of and their practices in informed consent, and the frequency with which they encountered informed consent in their nursing practice. Relationships between the nurses' demographic and work-related characteristics and nurses' knowledge of and practices in informed consent were reviewed.

A total of 225 nurse respondents completed the questionnaire, "Nurses' Perceptions of Informed Consent". Data obtained in response to the open-ended questions in Section I, the multiple choice questions in Section II, the Likert scale responses in Section III, and the demographic information in Section IV, were used to describe nurses' knowledge of and practices in informed consent.

Nurses' Knowledge of Informed Consent

Overall, nurses were able to correctly identify the different types of consent, the patient characteristics necessary to be able to make an informed consent, and the elements of information that are required for consent to be informed. Knowledge of the responsibility for information disclosure was well recognized by nurses; however, the role of witness to informed consent and the documentation of informed consent was inconsistent. Nurses' knowledge of patient rights in informed consent appeared to be consistent in all areas except the right to waive information.

Types of Consent

The responses indicated that the majority of nurses, especially those working in general medicine, were able to correctly recognize implied consent, verbal agreement, and signing a form to permit a test, as valid types of consent. Interestingly, approximately one-half of the nurses thought that submitting to a test, procedure, or treatment on the physician's recommendation was a valid form of consent. The latter example reflects a paternalistic attitude, and the patient who acquiesces or surrenders to the physician's decision may not actually be consenting or giving their approval to have the test, procedure, or treatment. The descriptions of consent in the literature indicate that all the types of consent should be associated with some form of information giving and decision-making on the part of the patient, and not just agreement with a physician's decision (Sim, 1986). The ultimate decision to undergo a test, procedure, or treatment is to be made by the patient based on an understanding of the related information and not solely on the physician's recommendation.

In the literature, some authors distinguish a difference between consent which is legally correct and consent which is ethically correct (Arbeiter, 1988; Calfee et al., 1991; Cassidy & Oddi, 1986; Chamorro & Applebaum, 1988; Fowler, 1987; Murphy, May 1988; Newhouse, 1993; RNABC News, 1987; Rothman & Rothman, 1977; Taylor & Hobaugh, 1986). Two areas of informed consent were identified which considered this type of legal-ethical differentiation; that which involves disclosure of information and that which involves witnessing consent. A legal standard for disclosure of information is a "minimum level of expected behavior" whereas, an ethical standard would aim for a more "ideal" situation with more information provided than the minimum standard requires.

This legal-ethical description was reflected in the findings of this study. The majority of the nurses responding to the open-ended question, stated they thought there was a difference between legal and ethical consent. Nurses most frequently characterized legal consent as pertaining to signing the consent form, which would then serve to protect the physician from liability. Ethical consent was characterized as pertaining to the elements of information disclosure and the patient's understanding of that information. Other descriptions of ethical consent included consent that would be morally correct, and consent for the purpose of protecting the patient's rights.

Patient Characteristics

Very few nurses actually described patient characteristics as necessary or important when they defined informed consent, in response to the open-ended question in Section I of the questionnaire. Responding to the multiple choice item in Section II that described patient characteristics for informed consent, nurses correctly identified legal age, receiving sufficient information, being mentally competent, and having the ability to understand the information. Very few nurses thought the ability to speak English was an important patient characteristic for informed consent.

Elements of Information Disclosure

The majority of nurses recognized that certain fundamental pieces of information should be provided to patients for the purpose of an informed consent. Nurses agreed that information about the nature of the test, procedure, or treatment, the risks and benefits, the complications, the alternatives to the test, procedure, or treatment, the outcomes and anticipated recovery, and the reason for the test, procedure, or treatment were important. Nurses also agreed that knowledge of the risks and benefits of the test, procedure, or treatment and then the description of the test, procedure, or treatment, were the most important pieces of information. This was unlike the results found in a study by Whalen (1984) who looked at critical care nurses' opinions of informed consent related to the insertion of a pulmonary artery catheter. Nurses, in rank ordering statements related to the elements of informed consent, thought that discomforts related to the procedure and patient's rights were more important than risks and benefits.

Nurses working in general medical areas were more likely to describe the patient's personal decision and the need to know information as elements important in informed consent. This may reflect a difference in the clinical nature of the medical patients' illness from patients with conditions requiring a surgical intervention. It may be suggested that patients in a medical area may have more options for tests, procedures, or treatments, which would be of such a nature as to require more decision-making on the part of the patient.

Responsibility for Disclosure of Information

Nurses overwhelmingly agreed that the responsibility for disclosure of information is the physician's, specifically the physician who is performing the test, procedure, or treatment. This physician's responsibility for information disclosure is supported by similar descriptions in the literature (Brown & Evans, 1989; Hudson, 1991; Greenlaw, 1983; Murphy, May 1988; Newhouse, 1993; Silva & Zeccolo, 1986; Taylor & Hobaugh, 1986). Very few nurses thought that just any physician could get an informed consent; however, many nurses did agree that the responsibility for informed consent could be delegated to a medical resident. Interestingly, some nurses thought information disclosure was a nursing responsibility, although, the literature is fairly consistent in describing how nurses should not be the ones to provide information for the purpose of obtaining informed consent. Nurses may clarify and/or reinforce information that has been provided by the physician (Bujorian, 1988; Carney, 1987; Cote, 1981; Fabiszewski & Volosin, 1992; Greenlaw, 1980; Lynch, 1988; Murphy, May 1988; Varrichio & Jassak, 1989; Weikel, 1987).

Witness to Informed Consent

Nurses did not consistently agree on the items related to the role of witness to informed consent. Less than half of the nurses thought that the role of witness was only to observe the patient sign the consent form, and a similar number indicated that the role of witness to informed consent was to agree that the patient understood the information. Nurses employed in a general hospital setting were more likely to correctly identify the role of witness to consent as observing the patient sign his or her name. Diploma prepared nurses more frequently identified the physician performing the procedure or the nurse who witnessed the discussion, as appropriate persons to witness consent. It has been suggested that to have the physician performing the procedure, act as a witness to the patient's consent, would be a conflict of interest (Fiesta, 1991). Some nurses thought they should listen to the physician's explanation prior to acting as witness, and others perceived they should ensure that the information provided was correct. While this may appear to be a good idea for ensuring the patient has received necessary information, or for documentation, or for assessing patient understanding, it may not be physically possible for nurses to be present in all consent situations. These inconsistent role descriptions are similarly reflected in the literature; however, the traditional and legally accepted description of witness to informed consent is simply, to verify the patient's signature (Armstrong, 1988; Brooke, 1988; Brown & Evans, 1989; Chamorro & Applebaum, 1988; Creighton, 1986; Cushing, 1984; Greenlaw, 1983; Murphy, May 1988; RNABC News, 1987; Varricchio & Jassak, 1989; Weikel, 1987). It is apparent that nurses have a misunderstanding of witness to consent which may have an impact on their nursing practice because their perception is contrary to the legal opinion.

Knowledge of persons who can be a witness to informed consent was also poorly recognized by nurses. The majority of nurses thought a witness should be the nurse who was present during the discussion between the patient and the physician; contrary to the literature description where the only legal requirement for a witness is to attest to the authenticity of the patient's signature, not verify the patient's decision (Guido, 1988). Again, poorly recognized as a witness by nurses, although probably the best person to act as a witness in terms of risk management for informed consent, is that witness who is a relative of the patient (Fiesta, 1991).

Documentation of Informed Consent

Diploma prepared nurses perceived written documentation of informed consent to be important, and many nurses, especially those practicing in general medicine, agreed that written informed consent would assist patients to maintain their right to make a decision, as well as to protect physicians, nurses, and hospitals from liability. Curtin (1982) supports this finding by suggesting that the principle of informed consent is to help patients, while the consent form serves to protect health care providers. Documentation of informed consent was perceived by the majority of nurses to serve as evidence of a discussion between the physician and patient. Interestingly, many nurses also indicated that the consent form provided evidence of informed consent. Most consent documents do not contain any information that would describe the contents of the discussion, or attest to the patient's accurate understanding of the information provided. Also, the witness does not verify the patient's understanding; therefore, it would be difficult to state this document represents an "informed consent". The consent form simply provides evidence that some form of discussion took place on a particular day between the named individuals; however, it does not substitute for the consent "process" (Brown & Evans, 1989; Cote, 1981; Cushing, 1991; Hogue, 1985; Hogue, 1986; Holder & Lewis, 1981; Miller, 1990; Moskowitz & Moskowitz, 1986; Rozovsky & Rozovsky, 1990; Sklar, 1974).

The majority of the nurses in the study agreed that the consent form should include the name of the test, procedure, or treatment, the name of the physician performing the test, procedure, or treatment, the patient's signature, and a witness's signature. A few nurses speculated that information related to the risks involved and the expected benefits or prognosis should be included.

Patient Rights in Informed Consent

The majority of nurses viewed the receipt of sufficient information as the main patient right in informed consent, with the right to refuse or withdraw from treatment included. Few nurses recognized that patients have the right to refuse information that may be necessary for decision-making, and that this "waiver" of information is a legal "exception" to informed consent (Guido, 1988; Rosoff, 1981). Almost all the nurses recognized that a paternalistic pattern of practice where patients would receive only that information that the physician thought was necessary, is no longer acceptable.

Nursing Practices in Informed Consent

Nursing responsibilities in informed consent were identified in responses to various items in the questionnaire. The most frequently described nursing responsibility was to ensure patient understanding of the information necessary for informed consent. The "process" of informed consent was perceived to be ongoing patient and physician discussion for the purpose of patient decision-making. Disclosure of information, witness to informed consent, documentation of informed consent, and clerical duties were also areas that nurses perceived as a role for nursing practice in informed consent.

Understanding the Disclosed Information

The large majority of nurses thought a nursing role in informed consent was to ensure that patients understood the information that was provided. Nurses perceived they could explain the information in terms the patient could understand, they could clarify the information, and if necessary they could recall the physician to further explain the information if they thought the patient did not understand or was uninformed. Nurses practicing in general medicine were more inclined to see clarifying information as a nursing responsibility. The use of clarifying, reinforcing, or verifying information were cited in the literature as roles "within the domain of nursing" (Bujorian, 1988). A surprising finding, indicated that nurses who were frequently involved in informed consent (once or more that once a day), were more likely to notify the physician to further explain or answer questions regarding the information. This may suggest that nurses who are more experienced with informed consent are more aware of their nursing responsibilities and the physician's responsibilities associated with informed consent.

The "Process" of Informed Consent

Only a few nurses characterized informed consent as a process, when they defined informed consent in response to the open-ended question in Section I of the questionnaire. These nurses described actions they thought were part of this "process" in obtaining informed consent, to include using understandable language, providing opportunity to ask the physician questions, and allowing time for decision-making before signing the consent form. Nurses consistently agreed that patients could ask questions after the consent had been signed, and this may reflect the ongoing nature of information sharing in the process of informed consent. Almost all of the nurses strongly agreed with the statement that informed consent is a process of shared decision-making between the patient and the doctor, which reflects the literature descriptions of shared decision-making in informed consent (Carney, 1987; Greenlaw, 1983; Kyler-Hutchison, 1988; Sprung & Winnick, 1989; Taylor & Hobaugh, 1986). The majority of nurses also agreed that the discussion between the physician and patient was an important part of consent. This perception was not demonstrated in a study by Carney (1987), where nurses described the patient more as a passive receiver of information and not as an active participant in informed consent.

In response to the statement that signing the consent form was the most important part, the majority of nurses disagreed. This may illustrate that nurses do not perceive the consent form and the act of signing the consent form as the process of informed consent, and this would be consistent with their response that the discussion is the most important part of the process of informed consent.

Disclosure of Information

Knowledge of information disclosure practices revealed that nurses overwhelmingly agreed that the physician is responsible for information disclosure. However, head nurses more often described the person responsible for information disclosure as the physician who performs the procedure. Staff nurses may be answering the question related to their current experiences, which may not reflect the physician being responsible for information disclosure, as it is described in the literature.

Discrepancies in nursing opinion arose concerning the issue of providing information for the purpose of informed consent. Some nurses thought they could provide patients with the initial information, or additional information, and answer questions about the test, treatment, or procedure. This action however, assumes responsibilities of the physician and therefore, the legal liability for complete and accurate information; thus, nurses should be discouraged from providing patients with information (Murphy, May 1988). Nurses who assume responsibility for providing information for the purpose of informed consent put themselves and their employer at risk for liability (Miller, 1990; Rozovsky & Rozovsky, 1987). Nurses may answer questions and discuss information with patients as long as it does not go beyond that which has been already been discussed with the patient by the physician (Creighton, 1986; Fabiszewski & Volosin, 1992; Greenlaw, 1980; Hershey, 1965).

There was a trend for nurses who were employed in a rehabilitation hospital to be somewhat more likely to give patients information about risks and complications if they felt patients were inadequately informed. A similar trend was also seen among nurses whose place of residence was other than a large city (possibly implying their nursing practice was in a smaller center). These observations may reflect the different clinical nature of patients in a rehabilitation hospital, or a smaller hospital, where the need for procedures requiring informed consent may be fewer. In these institutions, nurses' experiences with informed consent and their awareness of their responsibilities in informed consent may be less, or nurses may be more accustomed to providing patients with information as part of patient education in rehabilitation. Another explanation may be the less frequent physician's presence in a rehabilitation hospital or in a smaller hospital, thus leaving much of the education and information responsibilities to nurses.

Witness to Informed Consent

The traditional function of witness is described in the literature as only verifying the patient's signature (Armstrong, 1988; Brooke, 1988; Brown & Evans, 1989; Chamorro & Applebaum, 1988; Creighton, 1986; Cushing, 1984; Greenlaw, 1983; Murphy, May 1988; RNABC News, 1987; Varricchio & Jassak, 1989; Weikel, 1987). However, some authors explain the nurse has a legal and an ethical duty to ask the patient if they have discussed the procedure with the physician, and if they understand the information (Chamorro & Applebaum, 1988; Newhouse, 1993; Taylor & Hobaugh, 1986). Nurses in this study appeared to attach more involvement to the role of witness than the legal description implies, especially when they most often described a witness as the nurse who listened to the physician's explanation.

Documentation of Informed Consent

Attitudes toward documentation of informed consent with a hospital consent form revealed that nurses generally agreed it should be done; however, there were differences in opinion about who was responsible for documentation. Only half of the nurses agreed that the physician should be responsible for documentation, many nurses disagreed, and many nurses appeared unsure whose responsibility it was. Documentation of informed consent however, was seen to be the physician's responsibility more often by nurses employed in a general hospital setting.

Nurses were divided over the idea that nurses should be present during the physician-patient discussion for the purpose of documenting what transpired. Cushing

(1984) disagrees with this suggestion saying this responsbility is "not nurses'" (Cushing, 1984). Some nurses' comments indicated that their ability to answer questions, clarify, and/or reinforce information related to the information that was provided by the physician, may be impaired unless they were present during the patient-physician discussion, or unless the nature of the discussion was well documented by the physician. Legal opinion recommends that the physician chart the nature of the consent in the physician's progress notes, which will serve to document the consent, as well as improve the credibility of the consent (Rozovsky & Rozovsky, 1990).

Clerical Duties in Informed Consent

Half of the nurses thought that getting the patient's signature on the consent form, independent of the role of witness to consent, was a nursing responsibility. Ensuring the consent form was properly completed with the correct information and that the patient had signed the consent form, were also perceived as nursing responsibilities in informed consent by the majority of nurses. These clerical duties are similarly described in the literature (Balkan, 1986; Copeland, 1979; Creighton, 1986; Miller, 1990; Newhouse, 1993; Regan, 1980; Rozovsky & Rozovsky, 1987; Rothman & Rothman, 1977; Sklar, 1974).

Patient Rights in Informed Consent

Nurses who live in areas other than a large city, appeared more able to identify patient's rights in informed consent. However, an interesting finding indicated nurses with more years of nursing practice were less likely to recognize patient rights in informed consent. Nurses with more years in nursing practice also indicated they had a responsibility to provide support for patients in their decision-making; however, on the other hand, diploma prepared nurses were less likely to perceive supporting patients in their decision, as a nursing responsibility. Nurses with more years in nursing practice were likely to perceive that patients were able to understand the information provided.

Nursing Implications

Nurses demonstrated a general knowledge of the types of consent, the patient characteristics necessary for informed consent, the elements of information that should be disclosed for the purpose of informed consent, and the responsibility for informed consent. The inadequacies in knowledge detected were most notably, the provision of information or additional information by nurses to the patient for the purpose of informed consent, the concept of witness to informed consent, and the responsibility for documentation of informed consent. Likewise, there appears to be no consensus in the literature related to these particular areas.

The literature consistently ascribes the responsibility of informed consent to the physician. Nurses do not have a role in providing information to patients for the purpose of obtaining informed consent for a medical or surgical procedure, especially if that information has not been presented first by the physician. Clarifying, reinforcing information, and assessing patients' understanding of the information to assist patients when their understanding may not be adequate, are responsibilities that are within the practice of nursing. An example of how nurses may be involved in the information process may be with the use of patient information sheets or "acknowledged information". Physicians and nurses could collaborate on the development of specific test or procedural information sheets which the nurse could give to the patient to read. After this, the patient would sign the sheet indicating he had received and read the necessary information, at which time the nurse could answer questions, clarify the information, or seek more explicit information from the physician. This example accomplishes some of the physician's responsibility to provide the necessary information for informed consent and allows the nurse the opportunity to assist the patient's understanding by clarifying or explaining the information without having to provide the information.

A better understanding of the concept "witness" to informed consent may assist nurses and physicians to have a clearer picture of each others' responsibilities and ensure a better process for informed consent. Education in the role of witness to informed consent may clarify some of those inconsistencies as to who may act as witness, the responsibility of the witness, and the legal and ethical obligations of the witness to informed consent. If the role of witness to the patient's signature is only to authenticate the patient's signature, this clerical function could be accomplished by other hospital personnel, such as the unit clerk. As well, if authenticating or witnessing the patient's signature on a consent form is not a legal requirement (Fiesta, 1991), then a suggestion may be to consider deleting this function from the consent document, thus eliminating much of the confusion and dilemma associated with witnessing a patient's consent. The traditional role of witness to consent may be in conflict with nurses' ethical obligation to protect the patient's right to an informed choice if they were to act as witness to the signature without regard for the patient's knowledge or understanding of the information that would enable him or her to make an informed decision.

The law states that informed consent is the responsibility of the physician, and that the liability for this responsibility cannot be delegated (Allen, 1990; Bujorian, 1988; Creighton, 1986); therefore, it is difficult to perceive a more effective person than the physician to be responsible for the documentation of informed consent. If physicians assume responsibility for documentation of informed consent, continuity of patient care may improve, as other health care professionals will have access to the proposed plan of treatment and knowledge of what has been discussed with the patient.

Experience in clinical settings provides effective learning. Although consent situations may not always be available for student involvement, simulated or hypothetical situations may be provided for learning experiences. Continuing education about informed consent, with content related to the requirements for informed consent, nursing and physician responsibilities, as well, legal and ethical aspects, may aid nurses in becoming more aware of informed consent and how they can assist patients to make an informed decision within the limits of nursing practice.

Investigation into the patient's role in informed consent may provide some insight into improving the process from the patient's point of view. Educating patients about their right to receive information, their right to ask questions, and their right to make a decision, may affect the roles and responsibilities of nurses and physicians in informed consent. Patient interviews or a patient satisfaction survey about informed consent could be conducted to assess patients' opinions on how much information they need or desire to know and patients' opinions on how well health care professionals are accomplishing their desire for information. A patient who actively participates during the information disclosure discussion with the physician may be the patient who will make an "informed" decision.

Conclusion

Descriptive information about nurses' knowledge of and practices in informed consent indicates a need for further research and education in the area of nursing and informed consent. This research and education may be targeted towards the role of witness to consent, disclosure of information, and documentation of consent, which appeared to elicit the greatest degree of disparity of knowledge. There appears to be a need to examine how informed consent is documented, and to see how this could be improved to meet the needs of health care professionals, while maintaining the quality of patient care and the legal requirements. Information disclosure practices for informed consent may be assisted by nursing through patient education. Examination of a cooperative physician - nursing role in informed consent may lead to the development of better methods of informing patients, and/or the development of educational materials which may assist information disclosure, with the goal being to enhance patient decision-making. Informed consent is not a finite procedure simply to be obtained as a part of patient care. It is a process that begins with the physician informing the patient about his or her diagnosis, and it continues with the physician suggesting a course of action, explaining the nature of this action, the risks, the complications, the benefits, the anticipated recovery, and the prognosis with or without the test, procedure, or treatment and with nurses assessing the patient's understanding of the information, assisting the patient to understand the information by explaining and clarifyingthe information. The process of informed consent is one of "informed choice" which should continue throughout the course of the patient's medical care.

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APPENDIX A

Letter of Introduction

University of Alberta
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Faculty of Nursing
3rd Floor Clinical Sciences Building

Dear AARN Member:

My name is Cheryl Kee. I am a graduate student in the Faculty of Nursing at the University of Alberta. I am doing a study about nurses' perceptions of informed consent. Identifying your knowledge of and practices in informed consent may lead to a better understanding of informed consent and help nurses improve their patient care.

Your participation in this study would involve completing the enclosed questionnaire. It will take about 30 minutes for you to complete. All replies will be anonymous and treated confidentially.

The researcher has paid the AARN to mail the questionnaire but the AARN has not necessarily endorsed the study. Your name has been randomly chosen and is unknown to the researcher.

Please return the questionnaire in the self-addressed, stamped envelope provided. Do not put your name on the questionnaire or the return envelope. This study is voluntary and your consent will be implied with the return of the completed questionnaire. The questionnaires will be safely stored in a locked filing cabinet. The information may be considered later for secondary analysis after permission has been received from an appropriate ethical review committee.

If you agree to participate, please complete and mail the enclosed questionnaire by June 30th. If you have any questions about this survey, please contact me or my supervisor at the telephone numbers below. A copy of the completed study will be available at the AARN library or the Faculty of Nursing, University of Alberta.

THANK YOU FOR YOUR ASSISTANCE IN COMPLETING THIS QUESTIONNAIRE

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APPENDIX B

Questionnaire

Nurses' Perceptions of Informed Consent"

NURSES' PERCEPTIONS OF INFORMED CONSENT

The following are examples to assist you in thinking about possible medical consent situations you may encounter.

EXAMPLE ONE

A patient is admitted to the Coronary Care Unit suffering from an acute myocardial infarction. He continues to have chest pain and the cardiologist advises a coronary angiogram to be done . The cardiologist explains the nature of the angiogram along with the risks, complications, and the possibility of further procedures or cardiac bypass surgery. The patient agrees to proceed and signs the hospital's consent form.

EXAMPLE TWO

A woman in labor enters the hospital for delivery of her second baby. She is told by the medical resident that an internal fetal monitor is required as routine care by her obstetrician. After questioning the need for this, she refuses to allow this procedure to be done until she speaks with her obstetrician.

EXAMPLE THREE

A young man is brought to the Emergency department after being involved in a motorcycle accident. It appears his leg is broken and the physician feels there may be internal injuries. X-rays are performed and it is recommended by the physician that he have surgery to fix his leg right away. The man agrees to surgery .. "anything to get rid of the pain."

EXAMPLE FOUR

A patient was admitted to the surgery floor for preoperative preparation for abdominal surgery. The night before the procedure the nurse gives the patient the consent form and asks the patient if he understands what he is going for tomorrow. The patient tells the nurse that the physician told him all about it "in his office" and then signs the form.

SECTION I

Please answer the following questions about informed consent. Your opinion and practices are the desired response.

ALL RESPONSES WILL BE CONFIDENTIAL

1.1 How would you define "informed consent"?

____

____

____

____

____

____

1.2 Do you consider there to be a difference between "legal" and "ethical" informed consent? Please explain your answer.

____

____

____

____

____

____

1.3 Do you feel nurses should have a role in informed consent? Please explain your answer.

____

____

____

____

____

____

1.4 A nurse is present during a discussion between a patient, Mr. A, and his physician. The physician has told Mr. A that he requires a bowel resection and proceeds to outline the risks and complications that are associated with this procedure. The physician then asks Mr. A to sign the consent form. After the physician leaves, Mr. A appears to be upset.

What could the nurse do in the above situation to improve, if necessary, the informed consent situation?

____

____

____

____

____

____

SECTION II

This set of questions concerns your knowledge and current practices regarding informed consent. Please check ALL the responses you feel may apply.

2.1 Which of the following situations are considered to be examples of consent?

___ a patient rolling up his sleeve for blood work
___ a patient verbally agreeing to have an X-ray
___ a patient submits to a test, procedure, or treatment because his doctor recommends it
___ a patient signing a form to permit a test, procedure, or treatment

2.2 What makes a consent "informed"?

___ receiving information about the test, procedure, or treatment
___ understanding the risks, complications, and alternatives to the test, procedure, or treatment
___ agreeing to the physician's decision regarding the test, procedure, or treatment
___ deciding on the test, procedure, or treatment based on personal choice

2.3 What patient characteristics are necessary before informed consent can be obtained?

___ the patient is of legal age (if required by the hospital)
___ patient must be able to speak English
___ the patient is able to understand the information the doctor is discussing
___ the patient is mentally competent
___ the patient receives sufficient information to decide
___ the patient is not unduly influenced by anyone in deciding

2.4 What types of information would be necessary to achieve an informed consent?

___ the diagnosis or nature of the illness
___ the nature of the test, procedure,or treatment
___ any material risks that are associated with the test, procedure, or treatment
___ any possible complications
___ the probability of the treatment's success
___ what will happen if you don't have the test, procedure, or treatment
___ alternatives to the test, procedure, or treatment
___ who will be performing the test, procedure, or treatment

2.5 Who do you feel should be giving the information for the purpose of informed consent for a medical procedure?

___ the nurse
___ the resident delegated by a responsible physician
___ any physician
___ the physician responsible for performing the test, procedure, or treatment

2.6 What does "obtaining informed consent" mean?

___ getting the patient's signature on the consent form
___ giving the patient the information necessary to decide
___ making sure the patient understands the information

2.7 What does witnessing a consent mean?

___ observing a patient sign his/her name
___ agreeing that the patient understands what he/she is consenting to
___ agreeing that the information given to the patient was correct
___ listening to the physician explain the test, procedure, or treatment

2.8 Who can witness a consent for a medical procedure?

___ the physician who will perform the test, procedure, or treatment
___ any physician
___ the nurse who listened to the explanation
___ any nurse
___ any hospital employee
___ a relative of the patient

2.9 What role does the nurse have in informed consent?

___ may give information related to risks and complications to help the patient decide
___ may help a patient understand information already given by the physician
___ may get the patient's signature on the consent form
___ may witness the patient sign the consent form
___ no role

2.10 Which of the following activities might a nurse be responsible for in nursing practice?

___ making sure the consent form is properly completed
___ making sure the patient has signed the consent form
___ making sure the patient understands what he/she is consenting for
___ making sure the physician has given the patient all the information that is needed for consent
___ recommending a specific test, procedure, or treatment

2.11 What should the nurse do if he/she feels that after signing the consent, the patient does not understand the information?

___ the nurse should give the patient more information about the risks and complications
___ the nurse should explain the information the patient was told in terms he/she can understand
___ the nurse should get the doctor to come back and repeat the information if necessary and to answer any questions

2.12 What do you feel are patient's rights in informed consent?

___ to receive sufficient information that is necessary to decide
___ to receive only the information that the doctor feels is important in deciding
___ to refuse any information but still make a decision
___ to change a decision or withdraw from treatment at any time
___ the right to refuse a test, procedure, or treatment

2.13 What is the value of a written informed consent?

___ protects the physician from getting sued
___ protects the nurse and the hospital from liability if something goes wrong
___ helps the patient maintain his/her right to decide about their test, procedure, or treatment
___ helps the patient in deciding the best test, procedure, or treatment for him/herself

2.14 What is the value of having a consent form?

___ provides evidence of informed consent
___ prevents the physician from being sued
___ provides evidence of some kind of discussion about the test, procedure, or treatment
___ eliminates any liability of the hospital
___ no value

2.15 What information should be included on the consent form?

___ name of the test, procedure, or treatment
___ the name of the physician performing the procedure
___ the risks involved with and without the test, procedure, or treatment
___ the expected benefit and prognosis
___ the patient's signature
___ the physician's signature
___ a witness's signature

SECTION III

This set of questions concerns your opinions on informed consent to a medical test, procedure, or treatment. Please indicate how strongly you AGREE or DISAGREE with each of the following statements by circling a response.

3.1 Informed consent is a process of shared decision-making between the patient and the doctor.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.2 The most important part of informed consent is the discussion that takes place between the patient and the physician.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.3 The physician who is performing the procedure is legally responsible for information disclosure, even if he/she is not the primary physician.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.4 The patient can ask questions about the test, procedure , or treatment even after he/she has signed the consent form.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.5 The nurse's role in informed consent is to clarify the information provided by the physician.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.6 Nurses can give the patient additional information about the risks and complications related to the test, procedure, or treatment, if the nurse feels the patient is not adequately informed.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.7 Nurses can give patients information about the test, procedure, or treatment only if it has already been discussed with the patient by the physician.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.8 Nurses should support the patient in their decision even if it is not in agreement with what the doctor recommends.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.9 Nurses can tell patients they have the right to refuse the test, procedure, or treatment.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.10 Patients have the potential for understanding information about the recommended test, procedure, or treatment.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.11 If patients are unduly anxious or in severe pain they are unable to give informed consent.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.12 The most important part of the informed consent is signing the consent form.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.13 It is necessary to document informed consent with the hospital's consent form.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.14 Documenting the occurrence of informed consent is the physician's responsibility.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

3.15 Nurses need to be present during discussions related to informed consent for the purpose of recording what occurred.

strongly agree	agree	not sure	disagree	strongly disagree
1	2	3	4	5

SECTION IV

This section pertains to your personal and professional background. Please check the appropriate response.

4.1 How frequently are you involved in informed consent situations?

___ rare (less than once per month)
___ occasional (1once per week)
___ frequent (once per day)
___ very frequent (more than once per day)

4.2 What is your highest completed level of education?

___ diploma
___ baccalaureate ___ other than nursing
___ master's ___ other than nursing
___ doctorate ___ other than nursing
___ other (please specify)________________________________

4.3 What is your current place of employment?

___ general hospital
___ rehabilitation hospital
___ other (please specify) ________________________________

4.4 What current nursing position do you hold?

___ staff nurse
___ head nurse/nurse manager
___ other (please specify) ________________________________

4.5 In what area do you primarily practice?

___ general medical
___ general surgical
___ emergency care
___ maternal/newborn
___ pediatrics
___ critical/intensive care
___ operating room/recovery care

___ rehabilitation
___ psychiatry/ mental health
___ oncology
___ ambulatory care
___ gerontology

___ other (please specify)________________________________)

4.6 How many years have you been actively practicing nursing?

Please insert the actual number of years ____________________

4.7 Where do you presently live?

___ large city (population over 100,000)
___ city (population less than 100,000)
___ town (population more than 3,000)
___ village (population less than 3,000)
___ other (please specify)________________________________

Any additional comments you may wish to make are welcomed and may be included in the space remaining on this page or on the back.

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE. PLEASE RETURN THIS IN THE ENVELOPE PROVIDED BY JUNE 30th..

APPENDIX C

Follow-up Postcard Reminder

Postcard Reminder

This card is a friendly reminder that your response to the **"Nurses' Perceptions of Informed Consent"** survey would be very much appreciated. Please return the questionnaire by **June 15th.**

Respondent's Address

APPENDIX D

Ethical Approval

Joint Ethics Review Committee, Faculty of Nursing, University of Alberta

University of Alberta
Edmonton
Canada T6G 2G3

Faculty of Nursing
3rd Floor Clinical Sciences Building

Certification of Ethical Acceptability for Research Involving Human Subjects

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NAME OF APPLICANT(S): Cheryl A. Kee, MN Candidate

TITLE OF PROJECT: "Nurses' Perceptions of Informed Consent"

The members of the review committee, having examined the application for the above-named project, consider the procedures, as outlined by the applicant, to be acceptable on ethical grounds for research involving human subjects.

April 28/93
Date

Linda Reutter
L. Reutter, RN, PhD
Acting Chair
Ethics Review Committee

The Ethics Review Committee is a Joint Committee of
The Faculty of Nursing, University of Alberta
and
The Nursing Division, University of Alberta Hospitals

APPENDIX E

Authorization Access

Executive Director of the Alberta Association of Registered Nurses

ALBERTA ASSOCIATION OF REGISTERED NURSES

11620 - 168 STREET
EDMONTON, ALBERTA
T5M 4A6
TELEPHONE (403) 451-0043
TOLL FREE IN ALBERTA
1-800-252-9392
FAX (403) 452-3276

FILE NO. -- 1800-04

April 19, 1993

Cheryl Kee
RR #5, Site 23, Box 6
Edmonton, Alberta
T5P 4B7

Dear Cheryl Kee:

Your letter of April 15, 1993 requesting access to the AARN membership list for the purpose of conducting a survey on the topic of informed consent is acknowledged.

I am pleased to advise you that your request has been granted.

Membership lists perse are never provided, but rather the request is accommodated by the use of the Association's mailing service. You will be charged for the costs associated with this mailing. I emphasize also that the granting of this request is not to be interpreted as an endorsement of the project by the AARN.

Please contact Joan Welch, Administrative Officer of this office, concerning your specific needs and she will provide for implementation.

Yours sincerely,

Jean Smith, RN, BScN
Executive Director

/hl

cc Joan Welch
Janet O'Donnell